IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

OKLAHOMA STATE AND EDUCATION EMPLOYEES GROUP INSURANCE BOARD, Plaintiff, vs. MERCK & CO., INC., Defendant.	)	**CASE NO. _____** **JURY TRIAL DEMANDED** **ATTORNEY LIEN CLAIMED**

COMPLAINT

COMES NOW OKLAHOMA STATE AND EDUCATION EMPLOYEES GROUP INSURANCE BOARD (hereinafter "Plaintiff") and files its Complaint against MERCK & CO., INC., (hereinafter referred to as "Merck" or "Defendant") for: violations of Oklahoma's Deceptive Trade Practices Act, Oklahoma's Consumer Protection Act, for unjust enrichment, negligence and gross negligence, negligent misrepresentation, fraud and deceit, breach of implied and express warranty, and product liability, each related to Plaintiff, beneficiaries of Plaintiff, and/or Plaintiff's agents' purchases of the drug VIOXX from May, 1999 until its withdrawal from the market on September 30, 2004. Vioxx, as compared to other drugs in its class, caused a high incidence of injury among those individuals who ingested Vioxx, including, but not limited to heart attacks, strokes, sudden cardiac death, or death.

I. PARTIES

1. Plaintiff, OKLAHOMA STATE AND EDUCATION EMPLOYEES GROUP INSURANCE BOARD is a governmental entity and created to administer and provide the health and prescription coverage for governmental employees. This case is a "Government Action" in that this suit is brought by or on behalf of a state, county, city and/or other government entity administering government public assistance programs against Merck & Co., Inc.

2. Defendant, MERCK & CO., INC., ("Merck", "the company" or "Defendant"), a foreign corporation licensed to do and doing business in Oklahoma, is a New Jersey corporation with its principal place of business in New Jersey. At all times relevant hereto, Merck & Co., Inc. was engaged in the business of licensing, manufactu'ing, distributing, and/or selling, either directly or indirectly, through third-parties or related entities, the pharmaceutical prescription drug Vioxx. Plaintiffs allege on information and belief that Merck & Co., Inc. does business in Oklahoma and that at all times relevant hereto it developed, manufactured, and sold in interstate commerce and in Oklahoma, the aforementioned product.

II. JURISDICTION

1. Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332, because complete diversity of citizenship exists between the parties and the amount claimed exceeds $75,000.00.

2. The Court has jurisdiction over Defendant, Merck, because it engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third-parties or related entities, the pharmaceutical prescription drug Vioxx. Plaintiffs allege on information and belief that Merck & Co., Inc. does business in Oklahoma and that at all times relevant hereto it developed, manufactured, and sold in interstate commerce and in Oklahoma, the aforementioned product.

III. VENUE

1. Venue in this cause is proper in the United States District Court for the Western District of Oklahoma pursuant to 28 U.S.C. §1391(b) because a substantial part of the events or omissions giving rise to the claims occurred in this judicial district.

IV. FACTS

A. Background

1. On May 20, 1999, the FDA approved the sale and distribution of Vioxx, the brand name for rofecoxib, by Merck.
2. Vioxx is a member of a class of pain relievers called non-steroidal anti-inflammatory drugs ("NSAIDs")
3. Other pain relievers in this class of drugs include, among others, aspirin, naproxen, ibuprofen, and diclofenac.
4. NSAIDs act to relieve pain and inflammation by inhibiting production of an enzyme called prostaglandin G/H synthase. This enzyme consists of two similar forms, cyclooxygenase-1 ("COX-I") and cyclooxygenase-2 ("COX-2"). In the

medical and pharmacological literature, COX-2 is generally associated with effects on pain and inflammation; and COX-I is associated with, among other things, platelet aggregation and the integrity of the gastrointestinal tract. Traditional NSAIDs inhibit both COX-1 and COX-2 enzymes. Traditional NSAIDs have been associated with negative gastrointestinal side effects including perforations, ulcers, and bleeding in the gastrointestinal ("GI") tract.

5. Merck distinguished Vioxx from other NSAIDs as a selective COX-2 inhibitor that only targets and inhibits the COX-2 enzyme to control pain and inflammation. Merck's working hypothesis and market theory was that Vioxx would decrease the GI complications commonly associated with traditional NSAIDs because it did not alter COX-1 enzymes, and reduce pain and inflammation by selectively inhibiting the COX-2 enzymes.

6. COX-1 and COX-2 both help to produce chemical messengers called prostaglandins: COX-1 produces thromboxane, which constricts blood vessels and activates platelets; COX-2 produces prostacyclin, which dilates blood vessels and is a potent anti-aggregator of platelets. Selective inhibition of COX-2 reduces systemic levels of prostacyclin and permits unopposed production of thromboxane, resulting in a prothrombotic state, or a tendency to clot. This increases the risk for thromboembolic adverse events like heart attack and stroke in patients taking COX-2 selective inhibitors like Vioxx.

7. Vioxx did not eliminate the risk of adverse GI side effects, including serious complications, perforations, bleeds, and ulcers in the GI tract. Additionally, unlike

nonselective cyclooxygenase inhibitor NSAIDs, Vioxx contributes to the aggregation of blood platelets, thereby increasing blood clotting. Most significantly, to an extent much greater than other NSAIDs, Vioxx significantly increased the incidence of adverse cardiovascular and cerebrovascular events, such as myocardial infarctions (heart attacks), ischemic strokes, hypertension, and deep vein thrombosis.

B. Merck Knew and Concealed the Risks of Serious Adverse Events Associated with the use of Vioxx when Planning Its Vioxx Pre-Marketing Clinical Trials.

1. The potential for both limited, or no, reduction in GI events, and increased cardiovascular ("CV") adverse events, was well-known to Merck before it marketed Vioxx. But Merck chose to ignore this risk and proceeded with the development of the drug. Faced with projected revenue losses as patents on its most successful products expired, Merck recognized that Vioxx was its best chance for continuing high profits, and rushed the drug to the market.

2. On December 16, 1994, Merck filed an Investigational New Drug Application (an "IND") for Vioxx with the FDA. This IND included data and analyses from approximately two years worth of pre-clinical testing.

3. In May 1996, Merck announced that it was developing a selective COX-2 inhibitor, publicizing it as miracle drug for arthritis sufferers. At the time, Merck faced patent expirations on three of its ten most successful drugs - Mevacor, Pepcid, and Prilosec, which represented $4 billion a year in U.S. drug sales.

4. At the same time, Merck faced significant competitive threats from Monsanto and Pfizer, who were, in combination, developing a competitive selective COX-2 inhibitor, Celebrex® ("Celebrex"), scheduled to hit the market months ahead of

Vioxx. Merck understood its precarious financial position - if Vioxx did not go to market quickly, Merck would face serious financial challenges.

5. To corner the huge NSAID market, Merck recognized the crucial need to demonstrate that Vioxx had significant superiority over the competition.

6. In 1996, Merck announced the initiation of its clinical trials for MK-966, the internal designation for Vioxx.

7. Early results of the clinical trials began to paint a disturbing picture of the reality of the dangers of Vioxx. In September 1996, nearly three years before the drug was marketed, the Vioxx Project Team Minutes acknowledged reports of cardiovascular (CV) adverse events, registering "another case of unstable angina in an early... clinical trial." Remarkably, the Merck authors of this document admit that they anticipated results like this, noting that "vascular adverse events are expected because COX-1 is not inhibited."

8. The next month, an updated report of this same trial showed that Vioxx was associated with three times as many serious CV adverse events as placebo. The Preliminary Report on Rheumatoid Arthritis Protocol 017 reported six (6) serious CV adverse events for Vioxx compared with two (2) for placebo. The Vioxx Research Management Committee concluded that "adverse events of most concern [in early Vioxx trials] were in the cardiovascular system (e.g., MI unstable angina...)."

9. After learning that Pfizer was initiating a large outcome study to support a post-launch label change indicating the GI superiority of Celebrex, Merck was forced to reconsider its own studies. Ultimately, Merck proposed a large-scale, long-term, double-blind study of gastrointestinal toxicity in patients taking Vioxx. That

study was intended to mimic the large-scale Celebrex clinical trial to be conducted by Pfizer. This Vioxx G.I. Outcomes Trial ("VIGOR") was designed specifically to demonstrate the GI superiority of Vioxx as compared to another of the NSAID competitors, naproxen.

10. In the VIGOR planning stages, Merck suspected that Vioxx might cause cardiovascular problems. On November 21, 1996, a Merck internal memorandum, discussing the design of the VIGOR trial, suggested that participants be permitted to use aspirin during the study to moot the cardiovascular risks of Vioxx because, "there is a substantial chance that significantly higher rates" of cardiovascular problems would be seen in the Vioxx group.

11. On February 25, 1997, Merck scientist Briggs Morrison sent another internal email about the design of the VIGOR trial. In that email, Morrison suggested that VIGOR participants be allowed to take aspirin to avoid flagging the cardiovascular risks of Vioxx. Unless patients in the Vioxx group could take aspirin, he warned, "without COX-1 inhibition you will get more thrombotic events and kill drug [sic]."

12. Merck researcher Alise Reicin, now a Merck Vice President for clinical research, responded in an internal Merck email that Merck was in a "no-win situation": "This is a no win situation! The relative risk of [adverse GI events with] even low dose aspirin may be high as 2-4 fold. Yet, the possibility of increased CV events is of great concern (I just can't wait to be the one to present those results to senior management!). What about the idea of excluding high risk CV patients -- *i.e.* those that have already had an MI, CABG, PICA? This may decrease the CV

event rate so that a difference between the two groups would not be evident. The only problem would be - Would we be able to recruit any patients?"

13. Even years before approval of the drug, Merck met with the FDA officials to determine what type of studies would be necessary to demonstrate that Vioxx really possessed the safety benefits that Merck claimed the drug promised. (Minutes of End-of-Phase II Conferences with the FDA (May 22, 1996)). Senior FDA representatives advised Merck that in order to get the label it wanted, Merck would have to demonstrate the safety of the drug as compared to a placebo, or sugar pill, in a large scale outcomes trial.

14. At first, Merck contemplated comparing the safety of Vioxx to Tylenol (acetaminophen), because of Tylenol's placebo-like safety perception. However, two Merck executives "questioned the advisability of an acetaminophen arm, because the findings could highlight the favorable properties of acetarninophen." (COX-2 Inhibitor Consultants' Meeting Minutes (September 28, 1996)). As a result, Merck quickly scrapped the recommendation to compare Vioxx to Tylenol in such a trial.

15. In October 1997, Merck sponsored one of the clinical studies in healthy human subjects led by Dr. Garrett Fitzgerald from the University of Pennsylvania. The study was known as Protocol 023. During the study, Dr. Fitzgerald observed that patients taking Vioxx had significantly lower levels of prostacyclin metabolites in their urine than patients taking placebo. Dr. FitzGerald suggested to Merck that if Vioxx, a selective COX-2 inhibitor, was causing reduced prostacyclin levels in blood vessels, as well as in urine, then COX-2 inhibitors had the potential to cause increased blood clots and associated cardiovascular events.

16. Also in October 1997, Dr. John Oates of Vanderbilt, another Merck consultant and a scientist of international stature, wrote to Merck pharmacologist Dr. Alan Nies encouraging Merck to test the hypothesis that Vioxx was causing a hazardous depletion of COX-2 induced prostacyclin. The following month Dr. Oates wrote to Dr. Barry Gertz, another Merck pharmacologist, cautioning him that Merck should not assume that the reduction of prostacyclin caused by Vioxx occurred only in the kidneys. Dr. Oates warned that Vioxx was likely reducing prostacyclin at multiple sites throughout the body, including in blood vessels.

17. In December 1997, Merck appointed a "Task Force" to investigate the incidence of cardiovascular serious adverse events in the ongoing Vioxx clinical trials. The reason for the investigation was the unexpected result of an early clinical trial, which showed a decline in the levels of "PGI 2" (prostacyclin), the most potent of all inhibitors of platelet aggregation, but no inhibition of systemic thromboxane, in the urinalysis of patients on Vioxx. This imbalance triggered a concern over the potential for thrombotic events.

18. The Task Force agreed to investigate the incidence of thrombotic events by analyzing the ongoing osteoarthritis ("OA") trials. Because the trials were still blinded as to treatment groups, it could not be determined whether the adverse events in the database had occurred in the Vioxx, placebo, or compared to drug populations. Therefore, the Task Force designed a study in which cardiovascular events from all arms of the OA trials would be added together, and the combined groups' incidence rate would be compared to placebo patients from trials of other Merck drugs. An expedited time frame was established for completion of the analysis because of the rush to get Vioxx to market ahead of competitors.

19. In January 1998, the analysis pursuant to the Task Force plan showed a statistically significant increased relative risk of 2.16 for females in the Vioxx study versus the placebo group selected by Merck for comparison. These results constituted a clear signal of cardiovascular toxicity that should have triggered immediate investigation and concern. Instead, Merck made an after-the-fact claim that the placebo comparison group must have had an "atypically low" incidence of cardiovascular events, such that the higher rate in the Vioxx group was downplayed. Further, Merck changed the rules after the game had been played by deciding to compare the rate in the Vioxx group to a so-called "background" rate, even though no such comparison was stated in the plan for the study. Merck intentionally chose an inappropriate "background" rate for comparison, from a published study of older patients at high risk of cardiovascular disease. Based upon the result of this comparison, Merck incorrectly dismissed the signal as of no concern. Merck failed to disclose the results of this pre-marketing analysis, and instead, has misrepresented that it had no indication of cardiovascular risk before Vioxx was marketed.

20. Merck knew that due to the mechanism by which the drug inhibited COX-2, but not COX-1, use of Vioxx could result in increased platelet aggregation (blood clotting) and, thus, could cause increased rates of heart attacks and strokes. However, key to the successful marketing of Vioxx was the ability to claim that Vioxx was just as effective but safer than traditional NSAIDs and safer than Celebrex. This superior modeling would allow Merck to steal market share from Pfizer, which had beaten Merck to market with its own COX-2 inhibiting drug, Celebrex.

21. Merck failed to conduct any study prior to FDA approval demonstrating that Vioxx reduced the incidence of clinically meaningful side effects of NSAID therapy. At the time of approval, the FDA required that Vioxx carry the traditional warning concerning GI safety risks that accompanied all NSAIDs.

22. Even without a label that allowed Merck to legitimately claim superior safety, Merck and its representatives and agents misrepresented the safety profile of Vioxx to consumers, the medical community, healthcare providers, governmental entities and third party payers. Merck promoted, marketed, sold, and distributed Vioxx as a much safer and more effective pain reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

C. Merck Intentionally Overestimated the Number of Annual Deaths Attributed to NSAID Gastropathy in Order to Bolster the Image of Vioxx

1. In an attempt to inflate the perceived benefit provided by Vioxx, Merck has consistently overestimated the number deaths attributed to NSAID gastropathy. In 1997, it was estimated that the annual number of GI deaths attributed to NSAIDs in United States was 7,600. Notably, this estimate predates Vioxx's introduction to the U.S. market.

2. Merck consistently and misleadingly represented that approximately 16,500 patients taking NSAIDs died from toxic GI side effects each year, citing a single published estimate using certain 1997 data from the Arthritis, rheumatism, and Aging Medical Information System. However, it was well known in the field of rheumatology that this estimate was not accurate for the general population.

3. Following the completion of the VIGOR trial, Merck produced a series of

"video news releases" about the study. These short clips amounted to tightly controlled "interviews" of Merck employees and paid experts who tout the drug's alleged GI protective effect with no mention of cardiovascular risk. During one remarkable exchange, Merck expert and investigator Dr. Loren Laine, a gastroenterologist and author of the VIGOR study, is encouraged to gloss over the fact that Merck's GI death estimate is an exaggeration.

4. When Dr. Laine reads through his script initially, he balks at perpetuating the Merck charade, telling the company's representative that "...those numbers, by the way, are totally incorrect and they're based on just extreme totally incorrect data. Everybody uses them because they sound good. They sound good, but it's the same person that keeps putting them out." Of course, the importance of making such an inflated claim is not lost on the good Doctor, who observes: "There's about five different reasons why those numbers are totally bogus, but I agree. It's out there in the common realm and everybody uses those numbers. I know, because it's a very impressive sound byte."

5. Undaunted, the Merck representative wondered aloud whether the clever wording in the script would protect Dr. Laine from being patently untruthful, asking: "Does it help that we're using the word associated with NSAIDs; does that sort of water it down a little bit?" But this does not entirely soothe his conscience. "No. I mean because the issue is -- part of the issue is the -- you just don't have an idea. I'm not saying it's actually wrong. The death rate is probably wrong. The hospitalizations may be right. Just the death rate is probably wrong, but anyway..."

6. Eventually, Dr. Laine relents, and agrees to finesse the delivery so as to lend support to a number he clearly knows is wrong, because as he himself noted, "it's a very impressive sound byte." "As long as we say it's estimated or reported, it's not me saying it," Dr. Laine rationalizes.

7. Dr. James Fries of Stanford, who studied the Arthritis, Rheumatism, and Aging Medical Information System database specifically to determine how the rates of hospitalizations secondary to NSAID gastropathy have changed in the past two decades found that the number of GI related hospitalizations for people taking NSAIDs had decreased every year from 1992 through 1998, suggesting that the 1997 estimate of 7,600 annual GI deaths related to NSAIDS decreased as well. Interestingly, Dr. Fries also found that the incidence of GI hospitalizations actually increased following the introduction of Vioxx to the U.S. Market.[2]

8. Compounding Merck's fraud is the fact that (whatever the number of GI-related NSAID deaths) a sizeable portion are attributable to the use of aspirin for cardiovascular prophylaxis. In a nationwide study of mortality associated with hospital admission due to severe gastrointestinal events and those associated with non-steroidal anti-inflammatory drug use, covering hospitals serving more than seven million patients, researchers concluded that as many as one third of all NSAID/aspirin related GI deaths are associated with the use of low-dose aspirin[3]. Plainly, Vioxx would have no effect on these events as it is not a substitute for low-dose aspirin.

9. When Merck submitted the New Drug Application ("NDA") for Vioxx some five months later, it made no mention of these concerns. Still, the FDA medical

officer tasked with reviewing the Vioxx NDA decided that the data for Vioxx were concerning, and concluded that "[w]ith the available data, it is impossible to answer with complete certainty whether the risk of cardiovascular and thromboembolic events is increased in patients on [Vioxx]."

D. Merck's Pre-Market Knowledge of Vioxx's Cardiotoxicity and Prothrombotic Effects.

1. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Merck long before the FDA granted market approval in May of 1999. By 1997, and prior to the submission of the New Drug Application (the "NDA") for Vioxx, Merck was aware that, by inhibiting COX-2, Vioxx altered the homeostatic balance between prostacyclin synthesis and thromboxane and thereby increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. Although all COX-2 inhibitors have this mechanism of action, Vioxx was the most selective COX-2 inhibitor on the market in 1999. Accordingly, it had the greatest potential to cause adverse cardiovascular and cerebrovascular events.

2. Nevertheless, on November 23, 1998, Merck submitted an NDA to the FDA for Vioxx, omitting information about the extent of the risks associated with Vioxx. Without a complete picture of the potential hazards associated with the drug, the FDA approved Vioxx on or about May 20, 1999.

E. Merck Engaged in Unconscionable and Deceptive Marketing Practices in Connection With the Marketing and Sale of Vioxx.

1. Merck's Pre-Release Marketing Campaign Catapulted Vioxx to Blockbuster

Status.

2. In anticipation of approval, Merck put into place one of the most massive marketing campaigns in pharmaceutical history. Once the drug was approved, scores of sales representatives fanned out across the country with samples, asserting that Vioxx had a better safety profile than other NSAIDs. At the time the drug was approved, Merck's labeling indicated that Vioxx, taken at the 12.5mg, 25 mg, and 50 mg daily dosage, "was associated with a significantly lower percentage of patients with endoscopic gastroduodenal ulcers than with treatment with ibuprofen 2400 mg daily."

3. From 1996 through 1998, Merck issued dozens of public statements that pre-publicized the efficacy and gastrointestinal safety of Vioxx. Merck's pre-release marketing campaign conveyed the uniform message that Vioxx provided safe and effective pain relief while omitting any mention of cardiovascular risks.

4. Merck galvanized its army of sales representatives. In the *Merck & Co., Inc. 1998 Annual Report,* CEO Raymond Gilmartin wrote that "[i]n 1998, to prepare for the introduction of Vioxx, as well as to meet other marketing challenges, we began adding 700 new and talented professional representatives to our already strong U.S. sales force."

5. Merck targeted consumers and private and governmental third party payors. In order to achieve formulary status/access for Vioxx which was equal to or better than Celebrex and branded NSAIDs, Merck recognized that placement on the formularies of the private and governmental third party payers was critical to successful market share.

6. The pre-launch price of Vioxx was 800% more than the competing non-selective NSAIDs that were equally as effective in alleviating pain and inflammation associated with arthritis. Therefore, in order to get and keep Vioxx on the formularies of the private and governmental third party payors, despite this extreme overpricing, Merck authored studies designed to demonstrate that Vioxx was more cost-effective than other NSAIDs as a result of its decreased GI toxicity. Merck sent summaries of its positive clinical findings to formularies to demonstrate that the increased cost of Vioxx was more than off-set by costs associated with GI toxicity.

7. None of the materials and summaries of clinical studies sent to private and governmental third party payors, medical care organizations, or prescription benefit managers even remotely raised the potentially devastating cardiovascular and cerebrovascular side effects.

8. Merck's pre-release marketing campaign showed positive results. Sales projections for Vioxx based on early orders and inquiries surpassed $2 billion per year. Merck based this calculation on a proposed wholesale price of $2.02 per tablet - about one hundred times the cost of a generic ibuprofen, generic naproxen, or aspirin.

F. FDA Approval of Vioxx

1. On November 23, 1998, Merck submitted a NDA for Vioxx to the FDA. The FDA gave priority to the review of Merck's Vioxx submission, including through its Arthritis Drugs Advisory Committee ("the Advisory Committee")

2. On April 20, 1999, the Advisory Committee recommended approval of Vioxx for the relief of the signs and symptoms of osteoarthritis and acute pain but, in light of Merck's failure to substantiate its claims of the GI superiority of Vioxx, required that its package insert bear the same GI warnings as traditional NSAIDs.

3. On May 20, 1999, the FDA accepted the Advisory Committee's recommendations and approved Vioxx for the relief of signs and symptoms of osteoarthritis, for the management of acute pain in adults and for the treatment of primary dysmenorrheal.

4. On August 19, 2004, the FDA approved a third indication for the use of Vioxx: treatment of the signs and symptoms of juvenile rheumatoid arthritis in patients aged 2 to 17 years of age.

G. Merck's Unprecedented Post-Launch Marketing Campaign

1. Within days of receiving market approval to launch the drug, Merck began to aggressively promote Vioxx. 4,500 Merck sales representatives were sent to detail the drug to physicians. Merck had a huge budget for targeting physicians and consumers. Merck recognized the need to increase public demand for the drug by convincing consumers and medical professionals of the purported superior safety profile and effectiveness. Merck's message was clear: Vioxx was safer than - and just as effective as - traditional NSAIDs.

2. In 2000, Merck spent nearly $161 million on direct-to-consumer advertising for Vioxx -- more than any other drug, more than PepsiCo spent to advertise Pepsi Cola, and more than was spent to advertise Budweiser beer. Over the next few years, until market withdrawal, Merck spent approximately $100 million a year to

continue to market Vioxx directly to consumers. As stated by U.S. Senator Grassley of Iowa, Chairman of the Senate Committee on Finance at a congressional hearing on Vioxx held on November 18, 2004: "It's been said that in the history of pharmaceutical advertising, Vioxx was one of the most directly-marketed-to consumers prescription drugs ever."

3. Merck marketed Vioxx as a safe and effective pain reliever, while conspicuously omitting any mention of increased cardiovascular or cerebrovascular risk. Merck's promotional campaign falsely touted Vioxx's benefits while concealing its true health risks through false and misleading direct-to-consumer advertisements, sales promotions, press releases, and lectures at professional conferences.

4. From the beginning of this post-launch campaign, Merck was on notice of the fraudulent nature of its marketing tactics.

5. On July 16, 1999, the FDA's Division of Drug Marketing, Advertising, and Communications ("FDA-DDMAC") issued a letter to Merck, warning that its advertisements failed to provide adequate risk information. The FDA-DDMAC informed Merck that certain of its Vioxx promotional materials were "lacking in fair balance or [are] otherwise misleading."

6. For example, Merck's direct-to-consumer print ad for Vioxx, which appeared in the July 7, 1999 issue of *El Nuevo Dia,* failed, *inter alia:* "to include risk information" or to provide "necessary information related to side effects, contraindications, and effectiveness." The FDA-DDMAC concluded that the materials violated the Federal Food, Drug and Cosmetic Act and its implementing regulations, and it urged Merck to cease making such representations

immediately.

7. Merck's massive and misleading campaign continued unabated.

8. On December 16, 1999, the FDA-DDMAC issued another letter to Merck, stating that its promotional pieces entitled "TEN REASONS WHY VIOXX IS BETTER THAN CELEBREX and "Vioxx vs. Celebrex Poem" were "false or misleading because they contain misrepresentations of Vioxx's safety profile, unsubstantiated comparative claims, and are lacking in fair balance." For example, Merck claimed that Vioxx was safer than placebo in the incident rate of gastroduodenal ulcers. FDA-DDMAC observed that: "this claim is in direct contrast with the approved product labeling (PI)," which showed that there was an increased risk of ulcers with Vioxx use as compared to placebo. The FDA-DDMAC: "object[ed] to this claim because it minimizes the GI warning associated with Vioxx and is inconsistent with the data in the PI."

9. With respect to Merck's "TEN REASONS WHY VIOXX IS BETTER THAN CELEBREX," the December 16, 1999 letter stated that the promotional material contained several unsubstantiated comparative claims of Vioxx with Celebrex, including the assertion that Vioxx was more effective and safer than Celebrex, even though this claim had "not been demonstrated by substantial evidence." The FDA-DDMAC concluded that Merck's claims were "misleading."

10. The FDA-DDMAC December 16, 1999 letter asserted that Merck had failed entirely in its promotional materials to include a "fair balance with respect to the content and presentation of risk information related to the use of Vioxx." The FDA-DDMAC stated that, in these materials, Merck had "not presented any risk information concerning the contraindications, warnings, precautions, or adverse

events associated with Vioxx's use."

11. Merck's internal documents also reveal its massive efforts to blitz doctors' offices with promotional material, while expertly training its sale representatives to dodge any questions regarding the safety of Vioxx.

12. "Dodge Ball Vioxx," was another Merck sales representative training bulletin. In "Dodge Ball Vioxx," there was a list of hypothetical questions doctors might ask the sales representative about Vioxx, such as, "I am concerned about the cardiovascular effects of Vioxx" or "the competition has been in my office telling me that the incidence of heart attacks is greater with Vioxx than with Celebrex." Merck's instructions to be followed in response to these questions consisted of but a single word: "DODGE!"

13. Merck's most egregious marketing deception to physicians was through a pamphlet called the "Cardiovascular Card," which was given to sales representatives to convince physicians that Vioxx did not increase their patients' risk of serious cardiovascular illness or death. Tile Cardiovascular Card indicated that patients on Vioxx were 11 times less likely to die than patients on standard anti-inflammatory drugs, and 8 times less likely to die from heart attacks. However, the card did not present any statistical tests of significance that are standard within the medical community, nor did it mention data from studies 085, 090, Advantage or VIGOR. Nor did the Cardiovascular Card include the results of a meta-analysis performed by Merck's own statistician, Deborah Shapiro, showing that when all data available in November 2000 were pooled together, that Vioxx was more than twice as likely to cause a heart attack as other NSAIDs, by aligning the bar graph in the CV card purporting to show that the risk

of MI with Vioxx was virtually identical to other NSAIDs. Furthermore, the results of Merck's Advantage trial, completed in March 2000, showed that prophylactic aspirin was unlikely to mitigate the risk of CV events in patients taking Vioxx who had a previous history of CV disease, but this finding was not included in the CV card. Instead, the information used on the Cardiovascular Card was pooled from pre-approval clinical trials that were conducted to test the efficacy of the drug to treat pain, not to assess whether the drug caused heart attacks.

14. The Cardiovascular Card omitted patient deaths that were known to Merck. The mortality data on the Cardiovascular Card showed that overall mortality in patients taking Vioxx is virtually identical to those taking placebo, but this did not include Alzheimer's studies mortality data: known by Merck statistician Deborah Shapiro to be 30 vs. 10 (Vioxx and placebo respectively) on January 29, 2001, and re-calculated by Merck statistician Joshua Chen on May 1, 2001, showing 38 deaths among people taking Vioxx compared to 16 deaths among an equal number of people taking placebo ($p = 0.001$). This p-value means that there are 999 chances out of 1000 that Vioxx increases the risk of death in this population. Not only did Merck choose not to include this information in the Cardiovascular Card so that physicians and the medical community remained uninformed about this most serious of all drug risks, but Merck went even further and presented outdated and virtually meaningless mortality data from short studies that had been pooled together and expressed misleadingly as deaths per 100 patient-years, when the average length of these studies was in fact 3 months or less-hardly enough time for differences in mortality to appear.

15. The FDA expressed "serious concerns" about the data on the Cardiovascular

Card. A FDA medical reviewer said that the relevance of Vioxx's pre-approval studies to the drug's cardiovascular safety was "nonexistent" and that it would be "ridiculous" and "scientifically inappropriate" to present this data to physicians. As new evidence continued to surface showing the cardiovascular risks of Vioxx, Merck relentlessly pressured its field representatives to push the faulty data on the Cardiovascular Card.

16. In October, 2001, Merck learned of the publication of an article stating that there was a higher reporting rate for adverse events relating to renal and cardiovascular effects in Vioxx as compared to Celebrex. Merck responded by conducting an internal analysis of reported adverse events for Vioxx and Celebrex. Merck's analysis showed a greater reporting rate of myocardial infarction, congestive heart failure, and related illnesses for Vioxx in comparison to Celebrex. Merck disregarded this signal of cardiovascular toxicity and failed to disclose it to the public. Instead, Merck blamed the result on an alleged discrepancy in the number of events entered into the regulatory database for the two drugs. As in the case of the Task Force analysis of 1997 and the VIGOR study of 2000, Merck once again searched for and found a reason to exonerate Vioxx in order to omit, suppress, and conceal material information about Vioxx's safety risks to keep it on the market.

17. In 2001, after the FDA Advisory Committee voted in favor of informing doctors of the increased incidence of cardiovascular events seen in the VIGOR study, Merck disregarded the vote and instead, instructed its sales representatives to continue to use the Cardiovascular Card with its inaccurate data.

18. U.S. Congressman Henry A. Waxman described Merck's total disregard for the FDA Arthritis Drug Committee's unanimous vote that physicians should have been made aware of Vioxx's cardiovascular results. In the *New England Journal of Medicine* ("NEJM"), Congressman Waxman wrote: "[t]he next day, Merck sent a bulletin to its rofecoxib sales force of more than 3000 representatives. The bulletin ordered, `DO NOT INITIATE DISCUSSIONS ON THE FDA ARTHRITIS ADVISORY COMMITTEE ... OR THE RESULTS OF THE ... VIGOR STUDY.' It advised that if a physician inquired about VIGOR, the sales representative should indicate that the study showed a gastrointestinal benefit and then say, `I cannot discuss the study with you,'"

H. The VIGOR Trial The Vioxx Gastrointestinal Research ("VIGOR") Study

1. In January 1999, Merck initiated the Vioxx Gastrointestinal Outcomes Research ("VIGOR") study comparing Vioxx's efficacy and GI safety profile to a traditional NSAID, naproxen, in more than 5,000 rheumatoid arthritis patients.

2. In October 1999 the VIGOR study's data safety monitoring board ("DSMB") held its first meeting, the committee chairman was Dr. Michael Wienblatt.

3. By early November 1999, at the second VIGOR DSMB meeting there were indications in the VIGOR study that Vioxx increased the risk of serious cardiovascular events. There were 52 serious cardiovascular events in "group A" compared to 29 in "group B" (RR =1.8, P=0.01). Despite clear statistical evidence of the risk of harm to patients in group A, the study was continued. By the

December, 1999 DSMB meeting the risks of serious cardiovascular events and death among people taking Vioxx was double that of the naproxen group.

4. On February 7, 2000 Dr. Weinblatt filed a financial disclosure form that says he and his wife owned $72,975 of Merck stock. As reported by National Public Radio, Dr. Wienblatt, was thereafter hired as a consultant to Merck in February, 2000 for $5,000 per day for 12 days of work over a period of 2 years. In 2000, when Dr. Wienblatt was a consultant to Merck on Vioxx, he was also president-elect to the American College of Rheumatology, which issued a set of guidelines for medical management of osteoarthritis of the hip and knee and in September, 2000 recommended Cox-11 therapy as the third preferred treatment, without mention or discussion of the cardiovascular risks then known.

5. Merck's scientists understood that the difference in cardiovascular events was so great that the probability that it could have arisen by chance was miniscule, and that it almost certainly involved some sort of risk inherent to Vioxx. Merck's preliminary internal calculations demonstrated a four-fold increase of acute myocardial infarction ("MI") with once-daily 50 mg doses of Vioxx compared with twice daily 500 mg doses of naproxen (0.4% compared with 0.1% with naproxen). In fact, retrospective analysis of the data demonstrated a five fold increase in heart attacks in patients taking Vioxx verses those taking naproxen.

6. Rather than acknowledge the increased risk associated with Vioxx, Merck hypothesized that the reason for the results was not that Vioxx increased the risk of heart attacks, but that naproxen reduced the risk of cardiovascular events by having a cardio-protective benefit, similar to (but far more powerful than) aspirin.

The final conclusion of the article merely emphasized the purported GI benefits of Vioxx over other NSAIDs, but failed to disclose the increased risk of serious cardiovascular complications overall, the 21% increased risk of serious adverse events overall, and the numerically greater risk of cardiovascular events in people taking Vioxx than the reduction of GI events in people taking Vioxx. Instead of presenting the results for serious cardiovascular complications, Merck instead presented their own post hoc outcome explanation of heart attacks. Even then, Merck failed to include 3 heart attacks that occurred in the VIGOR trial that would have fundamentally changed readers' impression of the risks and benefits of Vioxx, showing that even for their post hoc outcome measure of heart attacks, Vioxx significantly increased the risk of heart attacks for all people in the VIGOR trial whether or not they had a prior history of cardiovascular disease.

7. Merck's statistician on the VIGOR trial, Deborah Shapiro, stated in an April 29, 2004 deposition that she became aware of the additional 3 heart attacks around the end of May, 2000 and that she was aware of the enormous statistical import of those 3 heart attacks. So at that time, six months prior to the VIGOR article being published in NEJM, Merck's statistician and co-author of that article understood that the article misrepresented the outcome of the VIGOR trial in that the 96% of the VIGOR trial participants who did not have a history of cardiovascular disease were, in fact, at increased risk of heart attack due to taking Vioxx instead of naproxen. In other words, Deborah Shapiro was aware six months prior to its publication that the following sentence in the VIGOR trial article published in NEJM was not true "In the other patients [the 96% without a

history of cardiovascular disease] the difference in the rate of myocardial infarction between groups was not significant (0.2% in the rofecoxin group and 0.1 % in the naproxen group)." Had the NEJM article included the 3 heart attacks, it would have had to report that Vioxx significantly increased the risks of heart attacks for all study participant, whether or not the had a prior history of cardiovascular disease.

8. In June of 2000, at the pharmaceutical industry-sponsored European United League Against Rheumatism ("EULAR"), Merck scientist Dr. Claire Bombardier presented the VIGOR study. Her presentation highlighted the beneficial GI profile of Vioxx, and buried the critical evidence of Vioxx users' statistically significant increased hypertension and serious ischemic cardiovascular complication rate compared to naproxen users.

9. Merck continued to profit from its failure to disclose crucial health information for years after the last VIGOR study participant had ceased taking the medication. In November, 2000, Merck physicians published a study in the NEJM that again knowingly failed to report the severity of cardiovascular risks associated with Vioxx consumption, choosing instead to report the post-hoc outcome measure of heart attacks, and even then knowingly withholding 3 heart attacks from its statistical analyses. Inclusion of these 3 heart attacks in the article would have fundamentally changed the safety message and all but "killed the drug," exactly the fear expressed by Merck's Alice Reicin in 1997.

10. Although Merck knew about the additional heart attacks from the Vioxx group in May 2000, this information was withheld from the New England Journal of

Medicine ("NEJM") article, and was not included in the November 2000 publication. The editors of the Journal became aware of the additional heart attacks in 2001, when the FDA made the information public. Until November 2005, however, the Journal editors believed that these events were not known to the authors in time to be included in the final version of the article. However, during a deposition of Dr. Gregory Curfnan, Executive Editor of the NEJM, it became clear that two of the authors, who were employees of Merck (Drs. Alise Reicin and Deborah Shapiro), knew about the extra heart attacks four and a half months before the article was published.

11. Upon learning that the Merck authors knew about the three additional heart attacks months before publication, the editors of the Journal published an "Expression of Concern." Therein, the editors note that the addition of this data rendered the "conclusions in the article incorrect," and that exclusion of the events "resulted in an understatement of the difference in risk of myocardial infarction between [Vioxx]... and...naproxen."

12. While publicly proclaiming that Vioxx did not increase the risk of serious cardiovascular events, Merck conducted an in-house review of nearly every study the company had performed on the drug to see if the VIGOR result was an anomaly. The Vioxx Preliminary Cardiovascular Meta-Analysis was designed to estimate the relative risk of thrombotic cardiovascular events in patients treated with Vioxx in comparison to those treated with nonselective NSAIDs. This analysis showed that Vioxx more than doubled the risk of heart attack when compared with NSAIDs. Incredibly, this analysis was never provided to the FDA,

though Dr. Scolnick has since admitted that it should have been provided.

13. In addition to this alarming data comparing Vioxx with NSAIDs, Merck had compelling data showing significantly increased risk when the drug was compared with placebo. Dr. Eric Topol, former Chief of Cardiovascular Medicine at the Cleveland Clinic has explained in a deposition that a placebo-controlled study completed about the same time as VIGOR, Protocol 090, clearly showed an increased risk for CV events: "to me, that study has been overlooked. It has, in many ways, extraordinary significance in the clinical development of Vioxx. And the reason is that this study had 978 patients ... [who] were randomly assigned to Vioxx, a medicine called nabumetone or known as Relafen, which isn't used very much, or placebo. And so what they had were these three arms tested with only 12-and-a-half milligrams of Vioxx. So, it's a very low dose of Vioxx ... And what is so striking about this trial is that it has, at the end of six weeks of therapy, a statistically significant 760 percent excess of heart attacks.... And the point being is that if you see that trial in replication with the problems with VIGOR, you have a very serious problem."

14. Had prescribing physicians and the medical community at large known that Vioxx increased the risk of heart attack for all persons taking it instead of naproxen, Vioxx would have been very rarely, if ever, prescribed. To put this in perspective, the actual risk of causing a heart attack in persons with no cardiovascular disease was greater than the benefit in preventing heart attacks conferred by prescribing a statin to persons with cardiovascular risk.

15. In the months that followed the publication of the VIGOR results, Merck

continued to maintain in many different forums and diverse ways that Vioxx had a satisfactory cardiovascular safety profile. Through direct-to-physician sales representative speeches to physicians, Merck spun the VIGOR results by claiming that they were either a result of chance or the result of the "cardioprotective effect of naproxen."

16. Merck scientists, however, knew this theory was categorically devoid of clinical support. In fact, a month after first seeing the VIGOR data, Dr. Edward Scolnick wrote that it remained to be seen if naproxen indeed lowered the risk of CV events, and acknowledged that only more work would clarify this aspect. A week later, he complained to other Merck executives that he was "in minor agony" over the VIGOR results, and grudgingly conceded that Merck would not know for sure about the risks of the drug until the company performed a cardiovascular risk study. None of these studies were ever done by Merck.

17. The November, 2000 NEJM article falsely reassured physicians and the medical community about the purported cardiovascular safety of Vioxx in patients with a history of cardiovascular disease. This false reassurance was perpetuated by Merck's widespread distribution of this article over the next several years, as discussed more fully below.

18. Despite having information regarding the cardiotoxicity of Vioxx, Merck did not mention the VIGOR results in its label for over two years. Further, Merck strongly objected to the warning language proposed by the FDA, and instead, lobbied and battled with the FDA to obtain the least restrictive label. Direct-to-consumer advertising continued unabated and undisturbed, failing to disclose

the true risk-benefit profile of Vioxx.

19. Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping the financial rewards of its deception and concealment. Merck engaged in a massive advertising campaign designed to increase its market share. As a result of this scheme, Merck reaped more than $2 billion in profits in the year 2000 alone, and the price of its stock rose 26% in the context of a declining market.

20. Then, on May 22, 2001, Merck issued a PR Newswire press release that selectively stated; "In response to news and analyst reports of data the Company released a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of Vioxx."

21. In response to information in 2001 demonstrating a significant increase in the risk of heart attacks as a result of taking Vioxx, Merck spokeswoman Christine Fanelle continued to publicize the fiction that the statistic could be accounted for by the cardioprotective effect of comparable drugs.

I. Merck Continued To Withhold Accurate VIGOR Results From The Health Community and The Public.

1. In March 2000, the results of the VIGOR Study came in, purportedly showing that Vioxx patients suffered fewer stomach problems than the naproxen group, but significantly more blood-clot-related problems - precisely the sort of result that Merck feared, as shown in internal documents dating back to 1996-1997. The heart attack rate in the Vioxx group appeared to be four times as high as the

naproxen group. (Later analysis would show it to actually be five times as high),

2. While this news was clearly devastating for Vioxx, it was precisely what the company expected to see. Indeed, almost immediately after receiving the VIGOR results, Dr. Scolnick admitted to his colleagues that Dr. Oates had been right about his concerns regarding selective inhibition of COX-2.

3. Merck continued to purposefully withhold this information from the public. In a news release that month, Merck said the VIGOR trial results were "consistent with" naproxen's favorable effects, implying that this could explain why Vioxx did not do as well.

4. Similarly, the next month Merck issued another news release, headlined "Merck confirms favorable cardiovascular safety profile of Vioxx." While acknowledging the Vigor results, it said other trials and data had shown "NO DIFFERENCE in the incidence of cardiovascular events" between Vioxx and a placebo or between Vioxx and older painkillers.

5. In April 2000, Merck responded to early news reports that Vioxx posed serious cardiovascular risks by simply denying that any such risks existed: "Extensive review of data from the completed osteoarthritis trials and on-going clinical trials with Vioxx ... have shown *no difference in* the incidence of cardiovascular events, such as heart attack, among patients taking Vioxx ..." (emphasis in original).

6. In June 2000, the same month that Merck released the results of the damaging VIGOR study to the FDA, Merck announced that the trial results were "consistent with" naproxen's cardio-protective effects. Contrary to Merck's assertions, no clinical study had ever proven that naproxen had a cardio-protective effect. According to a report from the FDA's Center for Drug Evaluation and Research released the day Vioxx was withdrawn from the market, naproxen would have had to be one of the most potent and effective cardioprotectants known in order to legitimize Merck's interpretation of the VIGOR results. Thus, not only was Merck's justification baseless and incorrect, but a recent naproxen study further revealed that the opposite may be true.

7. Not surprisingly, not even Merck's own advisors supported the naproxen hypothesis. A month before the first deceptive press release, one of Merck's top consultants, Dr. Carlo Patrono, considered one of the finest pharmacologists in the world, had admonished the company against propounding this theory to rationalize the VIGOR results. Dr. Patrono explained that the CV effect could not be attributed to naproxen for two reasons: first, there was a weak pharmacological basis and no epidemiological evidence for the theory; second, for naproxen to be the explanation, it would have to be three-fold better than aspirin at preventing heart attacks. This sentiment was echoed by another Merck consultant, Dr. Laurenzi Martino, who cautioned Merck that the presentation of the VIGOR data should not mislead the medical community into thinking that the difference in CV events could be explained by the antithrombotic effect of

naproxen, which was not demonstrated by any clinical evidence.

8. Also in June 2000, Merck minimized the results of the VIGOR study in a promotional conference by falsely asserting that Vioxx posed no greater risk of heart attacks than its competitor drug, Celebrex. Merck's representative stated: "Now if you remember the crude [heart attack] rate of Vioxx in VIGOR that number was 0.4 percent which is basically the same or in fact a little bit less than the crude [heart attack] rate of Celebrex in [the Celebrex Long-Term Arthritis Safety Study] CLASS which is 0.5 percent," This comparison was false and misleading because the studies had different patient populations, with the Celebrex CLASS trial including patients at higher risk for heart attacks.

J. Merck Continues to Dodge Disclosure of Vioxx Cardiovascular Risks Even When Faced with Additional Pressure from the FDA.

1. In the face of mounting evidence that Vioxx was associated with an increased risk of serious cardiovascular adverse events, Merck *fought* with the FDA to keep a warning about this data out of the drug's label. The company's sales forecasts show plainly why it took this action. Merck predicted that including a description of cardiovascular risks in the Warning section of the label, as opposed to Precaution section, would cost the company $1 billion per year in sales.

2. The FDA sought the cooperation of the company in presenting all available evidence in an open and forthright forum. To say that Merck failed to comply is putting it mildly. After the slick presentation of the VIGOR data by the Merck scientists, MRL President Ed Scolnick exclaimed that the Merck representatives at the meeting made the FDA officials "look like grade D *high* school students."

3. In February 2001, the FDA presented its analysis of the VIGOR data to an FDA Advisory Committee. The analysis showed that the number of people who experienced a GI complication (defined inclusively as a "perforation, ulcer, or bleed") while taking naproxen was about double the number for Vioxx takers. In truth, the increase in the number of serious cardiovascular complications in people taking Vioxx was even greater than the number of serious GI complications in people taking naproxen. In fact, in terms of overall safety, there were 21% more serious complications overall (including cardiovascular, GI, and everything else) in the people taking Vioxx than in the people taking naproxen (p0.03). In terms of hospitalizations, another indication of the incidence of serious illness, there were 28% more hospitalizations in patients who were taking Vioxx than in those taking naproxen". Specifically, there were 20 fewer hospitalizations for GI complications, but there were 41 more hospitalizations for cardiovascular complications in people who were taking Vioxx than in those taking naproxen. This data was not included in the NEJM article, nor in the FDA briefing documents, was never included in the Vioxx label, and was not included in the Dear Doctor letter that Merck sent out in 2002. Once again Merck withheld critical safety information from physicians and the medical community showing that Vioxx, rather than being safer than naproxen (the purported reason for using Vioxx at all), was actually significantly more dangerous.

4. Even these dismal safety data overstate the purported benefits of Vioxx because 56% of the participants in the VIGOR trial were taking steroids (for their arthritis) in addition to Vioxx or naproxen. Steroids increase the risk of GI complications by themselves, and do so synergistically when taken in combination with an NSAID.

In the general population, to which the results of the VIGOR would be applied, no more than 3% are concurrently taking a steroid and an NSAID. If the purpose of the VIGOR trial had genuinely been to determine whether Vioxx offered a significant GI benefit over naproxen, the relevant patients to look at are the 44% who were not taking steroids along with either Vioxx or naproxen. Within this subgroup, there was a numerical, but not statistically significant, reduction in the less-serious category of GI complications (perforations, ulcers, or bleeds -- 'PUBs"). However, in terms of the more-serious category of GI complications (perforations, obstructions, or bleeds - "POBs"), there was not even a numerical reduction in patients taking Vioxx compared to those taking naproxen (10 vs 9).

5. In February 2001, a full 19 months after Vioxx went on the market; the FDA published a Memorandum on the Vioxx cardiovascular safety data gathered during VIGOR. In this memorandum, the FDA concluded that there, "is an increased risk of cardiovascular thrombotic events, particularly [heart attacks], in the [Vioxx] group compared with the naproxen group." The FDA considered and rejected each of the defenses raised by Merck to explain the statistically significant increase of cardiovascular incidents among Vioxx users.

6. Merck immediately responded to the FDA's Memorandum with a press release announcing its confidence in "the excellent safety profile of Vioxx."

7. In February 2001, the FDA also concluded that Merck should add a cardiovascular warning to its Vioxx packaging: "it would be difficult to imagine inclusion of VIGOR results in the [Vioxx] labeling without mentioning cardiovascular safety results in the study description as well as the Warnings sections." Merck responded immediately with a press release directly

contradicting the FDA's findings by claiming that: "there was no difference in cardiovascular mortality between the groups treated with Vioxx or naproxen... [and] no *difference in* the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx ..." (emphasis in original).

8. Behind closed doors, Merck entered into negotiations with the FDA concerning the warning language to be used in its Vioxx labeling. FDA officials wanted to highlight the cardiovascular risk prominently on Vioxx's label. Merck resisted, complaining that the FDA was putting more weight on the negative findings than on the positive gastrointestinal aspects.

9. Merck's position in these negotiations was resolute and characterized by opposition towards any label change and a continuing denial of the dangers of Vioxx by upper-level management, facing bleak sales forecast if a warning were issued. In April 2001, MRL President Ed Scolnick blasted the FDA review system as an anachronism and threatened he would go over the head of FDA officials who wanted a new Vioxx warning label to senior FDA official Janet Lumpkin, or to his contacts at Health and Human Services, if need be. Scolnick then reminded his colleagues that he had "never seen being nice to FDA pay off."

10. In October, Merck received FDA's proposed label change for Vioxx, incorporating the changes which the agency felt simply had to be implemented. The proposed label included modest language in the Warning section which urged physicians to use caution when prescribing Vioxx to patients "at risk of developing cardiovascular thrombotic events" and in patients with hypertension. The Warning reported the five-fold increase in heart attacks from VIGOR and, critically, pointed out the consistency between the VIGOR results and those of

the ADVANTAGE trial. This would have warned doctors that VIGOR was not an anomaly caused by naproxen's phantom cardioprotective effect. Merck's internal response to the FDA's temperate proposal was fierce in its opposition. Scolnick and Anstice traded e-mails about it, with Scolnick firing first, assuring Anstice that "[Merck] will not accept this label." Anstice responded, calling the suggested changes "ugly," a description that apparently was not colorful enough for Scolnick, who ratcheted up the rhetoric: "It is ugly cubed. They [the FDA] are bastards." The next month, Dr. Scolnick told his successor at Merck, Dr. Peter Kim, that he would "never sign off on a CV warning."

11. The reason for Merck's refusal to add the FDA's proposed warning is simple: warning about the risks would have cost the company hundreds of millions in sales. Merck carefully studied the effect a warning would have had on sales of Vioxx, going as far as creating sophisticated forecasts to determine the damage in dollars. In September 2000, six months after learning the results of VIGOR, and a year and a half before any change was made to the label to reflect this data, Merck executives had determined that if the company was unable to neutralize safety concerns about Vioxx, it would lose $437 million in sales in 2001 alone. A year later, these same executives determined that the addition of a warning, as opposed to a precaution, would cost the company $1 billion in annual sales.

12. While these negotiations ensued, starting on May 22, 2001, Merck issued the first of a relentless series of publications publicizing the "favorable cardiovascular safety profile of Vioxx." In the first release, disregarding the results of its own trial and the FDA's review, Merck repeated: "there was no

difference in cardiovascular mortality between the groups treated with Vioxx or naproxen... [and] *no difference* in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx ..." (emphasis in original). These statements were repeated again and again in countless continuing medical education symposia and complemented by numerous papers in peer-reviewed medical journals authored by Merck employees and paid consultants, all of which attempted to debunk concerns about the adverse cardiovascular effects of Vioxx. The rate Merck was purchasing reprints of the falsely reassuring November 2000 NEJM article was accelerating and reached more than 549,000 reprints purchased in 2002.

13. Simultaneously, Merck continued to instruct its sale representatives to ignore the safety risks. For example, in June 2001, at the 119th Annual Meeting of the Maryland Pharmacists Association in Ocean City, Maryland, a sales representative attempted to explain away the VIGOR study's finding that Vioxx increased the risk of heart attack by stating that it was due to the fact that naproxen works like aspirin by inhibiting clotting and platelet aggregation. This had no basis in fact.

14. Similarly, at an Annual Meeting of the American Society of Health Systems Pharmacists in Los Angeles, California in June 2001, a Merck sales representative represented that Vioxx's greater rate of heart attacks in the VIGOR study was because of naproxen's cardioprotective properties. Again, this had no basis in fact.

15. Finally, on September 17, 2001, the FDA's DDMAC issued a `WARNING LETTER" ("2001 Warning Letter") to Raymond Gilmartin, President and CEO of

Merck, demanding that Merck correct false and misleading statements made in the course of its Vioxx promotional campaign. Specifically, the 2001 Warning Letter cited Merck's promotional audio conferences, a press release, and oral representations made by Merck's sales representatives to promote Vioxx. DDMAC stated that it had: "reviewed [Merck's] promotional activities and materials and has concluded that they are false, lacking in fair balance, or otherwise misleading" in violation of the FDCA and applicable regulations. Most, if not all, of the cited misrepresentations concerned Merck's failure to apprise the physicians and the public of Vioxx's danger of heart attacks and other cardiovascular complications. The FDA-DDMAC charged: "You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile of Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drugs (NSAID), Naprosyn (naproxen)."

16. The 2001 Warning Letter also cautioned: "You're minimizing these potential risks and misrepresenting the safety profile for Vioxx raise significant public health and safety concerns. Your misrepresentation ... is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for Vioxx that also misrepresented Vioxx's safety profile."

17. The 2001 Warning Letter delineated the following misrepresentations made by

and/or on behalf of Merck about Vioxx:

a. "Merck minimized Vioxx's risk of heart attacks in Merck's promotional audio conference, including conferences held on June 8, 2000, June 13, 2000, June 16, 2000 and June 21, 2000. Merck misrepresented that the use of naproxen decreased the chance of heart attack, as compared to Vioxx, because it thinned the blood. However, as the DDMAC observed, it could have just as easily been the case that Vioxx actually produced blood clotting. Moreover, Merck knew the difference between the heart attack outcomes for the Vioxx users while the naproxen users' outcomes had not yet been determined.

b. Merck concealed Vioxx's possible pro-thrombotic properties, which may reasonably explain the increase in adverse cardiac events.

c. Merck made inaccurate claims that the heart attack rate among people with history of cardiovascular disease for Vioxx and naproxen was .2% and .1% respectively. The 2001 Warning Letter declared that "the [heart attack] rate for Vioxx in this subpopulation was 12 [heart attacks] among 3877 patients (0.3%) as compared to 4 [heart attacks] among 3878 patients (0.1%) for naproxen.

d. Merck made false statements comparing the heart attack rate associated with the use of Vioxx in the VIGOR study to the crude heart attack rate of Celebrex in another study. Merck concealed the fact that the patient populations in the two studies were different in

that the VIGOR study excluded patients with heart problems, whereas the Celebrex study did not. Thus, it was more likely that the Celebrex study included patients with a higher risk for myocardial infarctions prior to their ingestion of Celebrex.

e. Merck concealed the fact that people in the VIGOR trial taking Vioxx's less expensive alternative, naproxen, suffered only 1/2 as many heart attacks.

f. Merck concealed the dangerous interaction of Vioxx with warfarin, an anticoagulant. For example, at an audio conference on June 16, 2000, Merck stated, "if you look at the thromboembolic events, it's very clear that these selective COX-2 inhibitors (of which Vioxx is a member) have the benefit of not having platelet aggregation and bleeding time, and therefore, can be used safely in terms of post-op and with Coumadin." This statement directly contradicts the precaution in the Package Insert and published in the Physicians' Desk Reference, which states: "In post-marketing experience, bleeding events have been reported predominantly in the elderly, in association with increases in prothrombin time in patients receiving Vioxx concurrently with warfarin,"

g. Merck concealed contraindications in patients who have experienced asthma, uticaria or allergic type reactions after taking aspirin or other NSAIDs.

h. Merck concealed the risk of serious GI toxicity such as bleeding,

ulcerations or perforation in patients taking Vioxx.

i. Merck concealed certain precautions for use in patients with liver and kidney disease, as well as failed to disclose information about which patient populations should not use Vioxx, including women in late-term pregnancy.

18. The FDA also warned Merck that its recent press releases: "confirming the favorable cardiovascular safety profile of Vioxx" were "simply incomprehensible" given the rate of heart attacks and "serious cardiovascular events compared to naproxen." Merck responded to this Warning Letter by pulling or revising the complained-of promotional materials, but persisted in refusing to include a cardiovascular warning in any of its direct-to-consumer advertisements. Merck's misleading statements had already infiltrated the market and influenced the ongoing demand for Vioxx.

19. The FDA expressed increasing concern about Merck's marketing of the drug to physicians and medical professionals. In the September 17, 2001 Warning letter, the FDA expressed concern over the representations made in a Merck-sponsored presentation by a doctor in June 2000. The doctor had said that the VIGOR trial showed that naproxen was "a wonderful drug" for reducing the risk of heart problems - not that there was anything wrong with Vioxx. Such statements, the FDA said "minimized potentially serious cardiovascular findings" of VIGOR.

20. In April 2002, after fourteen months of negotiations with the FDA, the new Vioxx label, which went into effect in April 2002, listed the good news about fewer upset stomachs first. Then, the Product Insert listed in the Precautions section -

not Warnings - two tables setting forth certain data from the Vigor study concerning increased incidence of cardiovascular events observed in the VIGOR study.

21. With the introduction of the April 2002 label, Merck issued a press release that minimized the importance of the risks it had been required to disclose: "the significance of the cardiovascular findings from [the VIGOR study] is unknown ... Merck is confident in the efficacy and safety profile of Vioxx." Merck was still engaged in a campaign designed to deceive the average consumer and the medical community by downplaying and suppressing any association between Vioxx and any serious cardiovascular risk.

K. Merck Attempts to Silence its Critics

1. During its ongoing effort to conceal the negative cardiovascular effects of Vioxx, Merck officials repeatedly lashed out against and threatened dissenting voices within the medical community.

2. In October 2000, a prominent COX-2 expert, Dr. Gurkipal Singh of Stanford University, who frequently gave lectures sponsored by Merck, repeatedly and publicly pressed Merck for more cardiovascular data on Vioxx. Merck responded by canceling several of Dr. Singh's presentations that it had been scheduled to sponsor. Still not satisfied, a senior Merck official, Louis Sherwood, called James Fries, MD, a Stanford University Medical School professor, to complain that Dr. Singh's lectures were "irresponsibly anti-Merck and specifically anti-Vioxx." According to Dr. Fries' letter to Mr. Gilmartin dated January 9, 2001, Sherwood

threatened that, "if this continued, Dr. Singh would flame out and there would be consequences for [Dr. Fries] and for Stanford." Dr. Fries responded by writing a letter to Merck CEO, Raymond Gilmartin, complaining about a consistent pattern of intimidation of investigators by Merck on Vioxx.

3. In that same letter, Dr. Fries reported that he had learned of repeated other incidents where employees of Merck had attempted to intimidate critics of Vioxx, and reported what he had learned to Mr. Gilmartin.

4. Perhaps the most aggressive action taken by Merck to attack its critics was against Dr. Joan-Ramon Laporte of the Catalan Institute of Pharmacology in Barcelona, Spain. In the summer of 2002, a publication of the Catalan Institute edited by Dr. Laporte criticized Merck's handling of Vioxx's cardiovascular risks. Soon after, Merck officials sent Dr. Laporte a "rectification" to publish, but Dr. Laporte refused to print a correction. After repeated efforts to correct the study, Merck filed suit in a Spanish court against Dr. Laporte and the Institute under a Spanish law that allows plaintiffs to demand a public correction of inaccurate published information. In January 2004, a judge ruled that Dr. Laporte's publication accurately reflected the medical debate about the cardiovascular safety of Vioxx, and ordered Merck to pay court costs. To punish Dr. Laporte, Merck withdrew funding for a pharmaceutical conference in Spain, which it had financed for the previous eight years, because the organizer would not remove Dr. Laporte from the list of speakers.

L. Merck Wrestles With Additional Studies Exposing Vioxx's Safety Concerns.

Following the VIGOR trial, Merck was confronted with study after study that demonstrated increasing evidence of Vioxx's serious and significant health risks.

a. The JAMA Study

1. Despite Merck's efforts to prevent negative information about Vioxx from seeing the light of day, some continued to question Vioxx's safety profile. The concerns that Vioxx significantly increased cardiovascular risk in Vioxx users were described by Drs. Mukherjee, Nissen and Topol in their August 2001 *Journal of the American Medical Association* ("JAMA") article. The authors specifically highlighted the dangerous cardiovascular adverse event profile of COX-2 inhibitors, particularly Vioxx.

2. In August 2001, Merck again publicly denied the validity of the adverse cardiovascular results of the VIGOR study, while persistently touting the gastrointestinal safety profile demonstrated by VIGOR. In two press releases, Merck attempted to refute the Mukherjee study, and repeatedly stated: "Merck stands behind the cardiovascular safety profile of Vioxx."

3. Merck indicated in its August 21, 2001 press release: "... Merck believes that extensive cardiovascular data already exist on Vioxx and that these data - which were not incorporated into the Cleveland Clinic's analysis -- suggest that there is no increase in the risk of cardiovascular events as a result of treatment with Vioxx."

4. The day before the Mukherjee JAMA article was published, Merck stated in a Bloomberg News piece: "We have additional data beyond what [Topol and the

Cleveland clinic study] cite, and the findings are very, very reassuring... Vioxx does not result in any increase in cardiovascular events compared to placebo.

5. The August 2001, JAMA published a paper by authors from the Cleveland Clinic Foundation, (the "JAMA Study") that included data from the briefing documents for the February, 2001 FDA advisory committee meeting that showed a significant increase in cardiovascular risk associated with Vioxx in the VIGOR trial."

6. On August 23, 2001, the day after the JAMA article was published, Merck stated in another press release: "The Company stands behind the overall ... cardiovascular safety profile of Vioxx."

7. Merck asked the Cleveland Clinic to run a rebuttal to this article. When it refused, Merck sent "Dear Doctor" letters to thousands of physicians nationwide that "strongly supported the cardiovascular safety profile" of Vioxx. Merck also sent "Dear Patient" letters to thousands of consumers nationwide (identified from a prescription database) wherein it specifically minimized the risk of "heart attacks and strokes" and emphasized that Vioxx was "innovative, effective and safe."

b. The Advantage Study

1. In 1999, Merck's marketing department commissioned its own 12 week clinical trial, as a promotional tool, to show that Vioxx caused fewer stomach problems than naproxen. The results of this trial, called Advantage, were available to Merck in March, 2000. The Advantage study compared Vioxx 25mg/day to naproxen and included people with a history of cardiovascular disease, allowing them to take low dose aspirin. The results of the Advantage trial not only

revealed a link between Vioxx and an increased risk of heart attacks and stroke, but also provided strong evidence that prophylactic low does aspirin did not reduce this increased cardiovascular risk of Vioxx in people with a history of cardiovascular disease. Faced with yet another threat to Vioxx's commercial success, senior Merck officials pressured their own researchers to change the trial results, so as to avoid concerns over the adverse cardiovascular effects of Vioxx.

2. Merck intentionally distorted and omitted data from the Advantage study so that it could continue marketing and selling Vioxx without an FDA warning regarding its known cardiovascular risks. Any such warning would have made Vioxx far less commercially attractive when compared to its closet competitor, Celebrex, which does not list heart risks on its label.

3. In October 2003, more than three years after the study's completion, Merck reported the results of the flawed Advantage study in a ghostwritten article published in the *Annals of Internal Medicine.* Although the article reported that five patients taking Vioxx had suffered heart attacks, the report failed to mention three additional heart-related deaths.

c. The Kaiser Permanente Study

1. In August of 2004, Dr. David Graham, Associate Director for Science, Office of Drug Safety, FDA Center for Drug Evaluation and Research, together with Dr. Wayne Ray and co-authors, presented an observational study at an international medical meeting, which evaluated the rate of cardiovascular events in patients

taking Vioxx versus Celebrex versus non-selective NSAIDs. This analysis was a retrospective study of the Kaiser Permanente database and was funded by the FDA. The results of this study were published in January, 2005 in the Lancet.

2. On August 25, 2004, Dr. David Graham reported that based on his study, Vioxx increased the chance of heart attacks in patients. This was the result of a retrospective study in which Dr. Graham and a team of researchers reviewed the medical records for approximately 1.4 million patients belonging to Kaiser-Permanente California HMO. Of these patients, 27,000 were taking Vioxx, and 40,000 were taking Celebrex. Other patients were taking other NSAIDs such as aspirin, ibuprofen and naproxen.

3. Dr. Graham studied the cardiovascular risks of Vioxx in his review. According to Dr. Graham's findings, which were reported at the international conference in Bordeaux, France: (1) Patients taking over 25 mg of Vioxx daily had a three-fold risk of suffering a heart attack or sudden cardiac death; (2) Patients taking lower doses of Vioxx were more likely to suffer serious cardiac problems compared to those taking Celebrex and other NSAIDs; (3) Naproxen increased the risk of serious cardiac events by 18%; and (4) Celebrex and ibuprofen had no effect on the risk of serious cardiac events.

4. In fact, Dr. Graham and his collaborators linked Vioxx to between 88,000 and 144,000 serious coronary events between 1999 through 2003. With an expected 44% case fatality rate for serious coronary events, this means that Vioxx was responsible for between 38,000 and 61,000 deaths in the United States during that time.

5. Shortly after the Graham-Ray study was presented at the international medical meeting, Merck issued a press release that it: "strongly disagrees with the conclusions of the observational analysis presented at the international medical meeting: Merck stands behind the efficacy, overall safety and cardiovascular safety of Vioxx."

6. Despite Merck's strenuous objections to the findings published from the Kaiser Permanente study, asserting that it was not definitive because it was not a full-blown clinical trial, one month later, Merck did an "about face" when its own clinical trial largely confirmed the results of Dr. Graham's study.

7. In the interim, Merck had failed to conduct a planned study to directly investigate Vioxx's cardiovascular toxicity, but instead chose to collect cardiovascular event data from studies designed for other purposes. In particular, Merck collected information about adverse events from trials to support applications to the FDA to expand the approved uses of Vioxx including the study that ultimately and belatedly caused the drug to be withdrawn.

d. The APPROVE Study

1. The Adenomatous Polyp Prevention on Vioxx ("APPROVe") Study was a multi-center, randomized, placebo-controlled study investigating the effects of Vioxx on the recurrence of neoplastic large bowel polyps in 2600 patients with a previous history of colorectal adenoma. Commencing in 2000, the APPROVe trial studied these 2,600 patients to evaluate whether Vioxx 25 mg doses prevented the recurrence of colorectal polyps in patients with a history of colorectal adenomas. The primary purpose of the study was to add another indication for the use of

Vioxx and thereby increase the market potential of Vioxx for previously unapproved uses. However, during the trial, Merck collected data concerning adverse events experienced by the subjects. As in other clinical trials, high-risk patients were intentionally excluded, which weakened the ability to detect significant differences in cardiovascular event rates, but starting in May, 2000, after the results of the VIGOR trial were available, patients taking low dose aspirin were allowed to participate in the study. Because of this change in the study design, people with a history of cardiovascular disease were included in the APPROVe study population, but they comprised a lower percentage of people than that found in the general population.

2. In mid-September 2004, APPROVe was halted suddenly when the data showed that. Vioxx caused a marked increase in the risk of heart attacks and strokes. In fact, patients taking Vioxx had double the risk of heart attacks as compared to patients taking placebo.

3. APPROVe revealed 15 cases of heart attack, stroke or blood clots over one year for Vioxx users as compared to 7.5 cases per year for those on placebo.

4. Merck has claimed since the release of the APPROVe results in September, 2004, that the risk of heart attack and stroke did not appear until after subjects had taken Vioxx for more than 18 months, based on so-called "adjudicated" events. However, Merck has concealed from the public its internal analysis of "investigator reported" cardiovascular events, which showed that the Vioxx rate exceeded placebo throughout the entire period of the study. Furthermore, Merck has concealed its internal analysis of such events showing a statistically significant risk for Vioxx versus placebo in the 0 to 18 month segment as well as

the 19 to 36 month segment of the study. In a graph of the "Kaplan-Meier cumulative rate curves" for Vioxx versus placebo, the Vioxx curve begins to exceed the placebo curve at approximately 2 to 3 months, and separates from the placebo incidence curve by an increasing margin for the remainder of the 36 month study. Merck's concealment of this data has been willful, intentional, deliberate, and designed to minimize its potential liability to Plaintiffs and the public. In fact, the NEJM issued a correction of this study deleting the language that stated that the increase in risk only started after 18 months.

M. Merck's Belated Withdrawal of Vioxx

1. On September 30, 2004, the Center for Drug Evaluation and Research of the FDA issued a Memorandum concluding that Vioxx has adverse cardiovascular effects, which were evident long before Merck's withdrawal of the drug:

> Rofecoxib [Vioxx] increases the risk of serious coronary heart disease defined as acute myocardial infarction and sudden cardiac death ...The observation of an increased risk was first noted with the VIGOR trial, where a 5-fold difference in risk was found between high-dose rofecoxib and naproxen. The manufacturer attributed this difference to a never before recognized protective effect of naproxen. To explain a 5-fold difference, naproxen would have had to be one of the most potent and effective cardio-protectants known. Three cohort studies and the present nested case-control study found no evidence of cardio-protection with naproxen. The three case-control studies that reported a protective effect were misleading. When analyzed in a manner comparable to the present study, no protective effect is shown.

2. On that same day, September 30, 2004, Merck issued a press release announcing the withdrawal of Vioxx based on "new" data indicating an increased risk of cardiovascular events, such as heart attack and stroke for those taking the drug eighteen months or longer. The decision came after the Data Safety

Monitoring Board for the APPROVe trial recommended that the study be stopped early for safety reasons based on the first three years of results. In November 1999, when faced with a very similar situation (significant increase in cardiovascular events in study patients in one group of the study), the Data Safety Monitoring Board made the opposite decision: allowing the trial to continue.

3. However, the totality of information available to Merck suggests that Vioxx should have been taken off of the market years before Merck's recall. In fact, an article in *The Lancet,* a respected British medical journal, pointed out that the "voluntary withdrawal of rofecoxib by its manufacturer, Merck, on the basis of a fairly small trial that was designed for a different purpose raises several questions." The critical question is why Merck waited so long to pull from the market a drug that it knew was associated with an unacceptably high risk of adverse cardiovascular and cerebrovascular events, such as heart attack and stroke.

4. This meta-analyses of randomized controlled trials and observational studies concluded that:

> Our cumulative meta-analysis of randomized controlled trials indicates that an increased risk of myocardial infarction was evident from 2000 onwards. At the end of 2000, the effect was both substantial and unlikely to be a chance finding. We found an increased risk of myocardial infarction in trials of both short and long duration, which is in contrast to the unpublished results from the APPROVe trial. [T]he reassuring statement by Merck, that there is no excess risk in the first 18 months, is not supported by our data... [D]ata from these studies indicate that if a protective effect of naproxen exists, it is ...not large enough to explain the findings of VIGOR. By contrast to our findings, two earlier meta-analyses from Merck Research Laboratories showed no evidence of a rise in cardiovascular risk or an increase in risk that was restricted to trials comparing rofecoxib with naproxen... To clarify

> the reasons behind the misleading results of Merck's meta-analysis of cardiovascular events in clinical trials of rofecoxib will be important ...If Merck's statement in their recent press release that `given the availability of alternate therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take' was appropriate in September, 2004, then the same statement could and should have been made several years earlier, when the data summarized here first became available. Instead, Merck continued to market the safety of rofecoxib."

5. In 2005, Dr. Levesque and her colleagues at McGill University published their study in the online edition of the *Annals of Internal Medicine,* to be followed by the print edition in April 2005. The McGill University study examined pharmacy prescriptions and cardiovascular adverse events among users of Vioxx and other pain medications in a large population of more than 100,000 elderly persons (mean age of 75; 55 years at entry).

6. Dr. Levesque reported that there were 5 times as many Vioxx-exposed case patients with MIs as reported by Dr. Juni in his study, and that Vioxx users had a significantly higher relative risk for MIs as compared to other NSAID users. The large size of the Levesque study database increases the reliability of the analysis, and these results provide strong, confirmatory evidence that the use of Vioxx is associated with an increased risk for an acute MI. The magnitude of the risk observed for users of Vioxx was even higher for individuals prescribed a dosage greater than 25 mg per day. However, even the patients who took lower doses of Vioxx had an elevated risk of a cardiovascular event. Further, Dr. Levesque wrote that, "[w]e have also shown that the cardio toxic effect of Rofecoxib previously observed in older and sicker populations extends to a healthier elderly population."

7. According to Dr. Levesque, "the totality of the current evidence confirms the

increased cardiovascular risk associated with Rofecoxib and the sagacity of its withdrawal," These results were consistent with the results of the VIGOR study and the APPROVe results, as well as the studies of Ray (2000), and Graham and Ray (2005).

8. In November 2004, the United States Senate Finance Committee held hearings on Vioxx and related drugs approved by the FDA and then withdrawn because of significant health risks. Dr. David Graham testified about his experience with Vioxx:

> Prior to approval of Vioxx a study that was performed by Merck, named 090, which found a nearly seven-fold increase in heart attack risks with low-dose Vioxx. The labeling at approval said nothing about these heart attack risks. In November 2000, another Merck trial named VIGOR found a five-fold increase in heart attack risk with the high-dose from Vioxx. About 18 months after the VIGOR results were published, FDA made a labeling change about heart attack risk. But it did not place this in the "Warnings" section of the labeling. Also, it did not ban the high dose formulation and its use. I believe such ban should have been implemented. In March 2004, another epidemiology study reported that both high-and low-dose Vioxx increased heart attack risks compared to CELEBREX, Vioxx's leading competitor. Our study found similar results. A study report describing our work was put on the FDA website. This report estimated that nearly 28,000 excess cases of heart attack and sudden cardiac deaths have been caused by Vioxx. I must emphasize to the committee that this is an extremely conservative estimate. FDA always claims that randomized clinical trials provide the best data. If you apply the risk level seen in the two Merck clinical trials, VIGOR and APPROVe, you obtain a more realistic and likely range estimates for the number of excess cases. This estimate ranges from 88,000 to 139,000 Americans. Of these, 30 to 40% probably died; for the survivors, their lives were changed forever. This range does not depend at all on the data from our Kaiser-FDA study. Indeed, Dr. Eric Topol at the Cleveland Clinic recently estimated 160,000 cases in the article that was published in the New England Journal of Medicine.

9. In February 2005, a 32-member FDA Advisory Panel conducted hearings to determine whether or not COX-2 inhibiters should be made available to the public

and, if so, on what terms. The Panel criticized the label change made by Merck in 2002, which the Panel deemed insufficient to warn the public about the cardiovascular risks of Vioxx use.

10. During the Panel hearings, the senior director of Merck Research Laboratories, Dr. Ned Braunstein, tried to portray Vioxx's dangerous effects as a class effect of all COX-2 inhibitors. This attempt to characterize the dangers of Vioxx as a class effect represents a critical admission of the risk of Vioxx use that directly contradicts Merck's prior statements and omissions about the safety and the unique characteristics of its product.

11. At the conclusion of the hearings, the members of the Advisory Panel, a third of whom had worked for Merck in the past, voted by the narrowest of margins (17-15) to recommend that Vioxx be allowed to return to the market, with severe limitations on use. If the panelists who had not previously worked for a pharmaceutical company had not voted, Vioxx world have been prevented from returning to the market by a margin of 14-8. To date, the FDA has not accepted the Panel's recommendations.

N. Merck's Institutes a Consumer Refund Program That Does Not Include End-Payors.

1. Merck publicly acknowledged on its website that it is responsible to reimburse patients for their unused portions of Vioxx. To this end, Merck has instituted a reimbursement program that is fundamentally flawed, does not fully and effectively reimburse End-Payors, and does not make them whole.

O. Merck's Continued Fraudulent Marketing Campaign Caused Active Concealment of Vioxx' Deficiencies and Inflated Payments by End-Payors for Vioxx.

1. As a result of Merck's claims, Plaintiff purchased and/or paid for Vioxx even though, at $72 for a monthly supply (in 1999, increasing to $128 for a monthly supply by February, 2004), Vioxx was much more expensive than other NSAIDs, which sold for $6.67 or less for the same month's supply.

2. To justify the disparity of Vioxx's pricing as compared to other NSAIDs and to ensure that physicians would prescribe and that third party payors would purchase and pay for the drug, Merck misrepresented the safety and efficacy of Vioxx and omitted, concealed, and suppressed the risks, dangers, and disadvantages of the drug. Consequently, Vioxx captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2000 alone, sales of Vioxx exceeded $2 billion, which represented 23% of the total NSAIDs market, despite the significantly higher cost of Vioxx as compared to other pain relievers in the same family of drugs.

3. Merck's deceptive and misleading marketing campaign resulted in inflated payments by consumers and third party payors, including Plaintiff for, in whole or in part, the costs of Vioxx. Millions of third party payors including Plaintiff, have already paid for, and/or purchased and consumed Vioxx at prices based on the proposed wholesale price, which was about one hundred times the cost of a generic aspirin. These third party payors paid more than they would have or should have because Vioxx was promoted and advertised as a premium drug with reduced side effects for the purpose of deceiving consumers and third party

payors about Vioxx's adverse cardiovascular and cerebrovascular effects.

4. In fact, the economic effects of being required by the FDA to disclose the side effects and cardiovascular risks of Vioxx were known to Merck. In its internal documents, Merck calculated and included the expected losses in Vioxx sales and market share that could be anticipated to result when Merck would be required to include the risks in the Vioxx label. The projections estimated, at least, a $229 million loss in sales in 2002 and a loss in market share of, at least, 10 to 20 percent. Merck continued its game of deception well into 2004, finally withdrawing Vioxx from the market on September 30, 2004, years after it knew of, but omitted, suppressed, and concealed the increased serious health risks associated with Vioxx use.

P. Merck's Settlement of Numerous Criminal and Civil Lawsuits with Governmental and Personal Injury Claimants.

1. In 2004, the U.S. Department of Justice ("DOJ") and the Securities and Exchange Commission ("SEC") launched investigations of Merck's handling of Vioxx. On November 19, 2004 a U.S. Senate Committee held hearings in its investigation of Vioxx. Governmental investigations continued for several years, with close cooperation between the DOJ, SEC, state attorneys general and other law enforcement entities including the Medicaid Fraud Control Units, and the Office of Inspector General of the Department of Health and Human Services ("HHS- OIG").

2. In February of 2007, Merck disclosed in its regulatory filings that the DOJ issued

a subpoena requesting information relating to the company's research, marketing and sales of Vioxx as part of a federal investigation under criminal statutes. The health-care-fraud unit of the US Attorney's Office in Massachusetts spearheaded the federal grand jury probe.

3. In November of 2007, Merck agreed to settle approximately 47,000 lawsuits by individuals who claimed they or their family members suffered injury or died after taking Vioxx. The $4.85 billion global Vioxx settlement is being overseen by U.S. District Judge Eldon E. Fallon of New Orleans.

4. In February of 2008, the DOJ announced a settlement for more than $650 million to resolve claims of fraudulent price reporting and kickbacks by Merck involving Vioxx. The settlement addressed allegations that Merck failed to pay proper rebates to Medicaid and other government health care programs and paid illegal remuneration to health care providers to induce them to prescribe the company's products. The allegations were brought in two separate lawsuits filed by whistleblowers under the qui tam provisions of the Federal False Claims Act, Under the two settlement agreements, the federal government was awarded more than $360 million, and forty-nine states and the District of Columbia over $290 million. As part of the resolution of the two cases, the HHS-OIG and Merck entered into a five-year Corporate Integrity Agreement including provisions designed to ensure that Merck will market, sell, and promote its products in accordance with all federal health care program requirements.

5. In May of 2008, Merck entered into a $58 million civil consumer fraud settlement with Attorneys General from 28 states and the District of Columbia. In addition to

payments to the states, significant remedial provisions of the settlement affect a broad swath of pharmaceutical company activities, including advertising and promotion, continuing medical education, drug safety monitoring boards, journal authorship and clinical trial posting. As part of the settlement, Merck agreed to: (1) Pay 58 million dollars to the states involved; (2) No longer engage in "ghostwriting"; (3) Refrain from using scientific data deceptively when marketing to doctors; (4) Delay any direct-to-consumer television advertising for a pain medication if recommended by the FDA; and (5) Submit all television advertising campaigns to the FDA before release for review and to adhere to any recommendations by the FDA.

Q. Merck Mispresented the Efficacy and Safety of its Drug Vioxx to Plaintiff, Plaintiff's Agent, Employees, and Beneficiaries; and/or to other Governmental Bodies

1. Merck, at all times Vloxx was on market, actively sought to directly induce Plaintiff's employees, agents and beneficiaries; physicians who prescribe drugs and are paid by Plaintiff; customers who received drugs from state agencies; agents of state entities who pay for drugs to Plaintiff's beneficiaries and citizens of Oklahoma; and other governmental entities-to purchase, prescribe, and/or use Vioxx.

2. Merck, at all times the drug Vioxx was on the market, actively misled Plaintiff's employees, agents and beneficiaries; physicians who prescribe drugs and are paid by Plaintiff; customers who received drugs from state agencies; agents of state entities who pay for drugs to Plaintiff's beneficiaries and citizens of

Oklahoma; and other governmental entities-to purchase, prescribe, and/or use Vioxx.

3. But for Merck's fraudulent, deceitful, and unethical conduct, Plaintiff's employees, agents and clients would not have included Vioxx in its list of approved drugs.

4. But for Merck's fraudulent, deceitful, and unethical conduct, physicians would not have prescribed Vioxx to clients for which Plaintiff paid and paid a premium price for Vioxx vis-à-vis other available medications.

5. But for Merck's fraudulent, deceitful, and unethical conduct, Plaintiff's beneficiaries would neither have requested nor been given Vioxx nor paid a premium price for Vioxx vis-à-vis other available medications.

6. But for Merck's fraudulent, deceitful, and unethical conduct, neither Plaintiff nor other governmental entities would have paid for the use of Vioxx by citizens of Oklahoma, nor paid a premium price for Vioxx vis-à-vis other available medications.

V. CAUSES OF ACTION AGAINST MERCK

A. FIRST CAUSE OF ACTION: UNFAIR TRADE PRACTICES

1. Plaintiff re-alleges and incorporates all preceding paragraphs of this Complaint as if fully set forth here, and further allege as follows:

2. At all times pertinent herein, the Defendant marketed, sold, and distributed Vioxx for use by consumers, including Plaintiff and citizens of Oklahoma;

3. The Defendant knew or should have known, even prior to market launch, that Vioxx had significant cardiovascular safety risks, and did not provide better effectiveness or GI safety than other NSAIDs;

4. The Defendant is liable to Plaintiffs under the Oklahoma law because it manufactured Vioxx and sold Vioxx to Plaintiff, Plaintiff's beneficiaries and citizens of Oklahoma in violation of the provisions of the Oklahoma Deceptive Trade Practices Act (ODTPA), Okla. Stat. tit. 78, §§ 51-55. Each of the previously described acts by the Defendant was "unlawful" in that they were unfair methods of competition and/or unfair or deceptive acts or practices in the conduct of Defendant's trade or commerce.

5. As set forth previously, the Defendant has used unfair methods of competition and/or unfair and deceptive acts or practices in the design, manufacturing, and/or marketing of Vioxx and in the course of its business, all of which are unlawful under ODTPA. *See Central Plastics C. v. Goodson*, 537 P.2d 330, 335-36 (OK 1975) (misleading advertisement is a violation of Okla. Stat. tit. 78, § 53(a)(2) and (5), and provides for damages under Okla. Stat. tit. 78, § 54(a)).

6. As a direct and proximate result of the Defendant`s wrongful conduct in violation of ODTPA, Plaintiff, its agents, its beneficiaries and intermediaries have sustained financial losses in amounts as will be established at the trial of this matter, including paying for Vioxx that they would not have otherwise paid and economic losses incurred by paying a premium price for Vioxx, as opposed to other viable, less expensive, pharmaceutical treatments. Plaintiff is entitled to recover from the Defendant all such losses.

B. SECOND CAUSE OF ACTION: VIOLATIONS OF OKLAHOMA CONSUMER PROTECTION ACT

1. Plaintiff re-alleges and incorporates all preceding paragraphs of this Complaint as if fully set forth herein, and further allege as follows:

2. Under the Oklahoma Consumer Protection Act (OCPA), "Deceptive trade practice" means a misrepresentation, omission or other practice that has deceived or could reasonably be expected to deceive or mislead a person to the detriment of that person. Such a practice may occur before, during or after a consumer transaction is entered into and may be written or oral. *See* Okla. Stat. tit. 15 § 752.

3. Under OCPA, a "Person" means a natural person, corporation, trust, partnership, incorporated or unincorporated association, or any other legal entity. *See* Okla. Stat. Title 15 § 752.

4. Under OCPA, a "Consumer transaction" means the advertising, offering for sale or purchase, sale, purchase, or distribution of any services or any property, tangible or intangible, real, personal, or mixed, or any other article, commodity, or thing of value wherever located, for purposes that are personal, household, or business oriented. *See* Okla. Stat. Title 15 § 752.

5. Under OCPA, an "unfair trade practice" means *any* practice which offends established public policy or if the practice is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers. *See* Okla. Stat. Title 15 § 752.

6. The Defendant continuously omitted, suppressed, and/or concealed material

facts concerning the dangers and risks associated with the use of Vioxx and the efficacy of Vioxx vis-à-vis other drugs on the market. The Defendant purposely concealed adverse studies, trivialized the seriousness of the risks associated with the use of Vioxx, and encouraged the use of this drug despite knowledge of the undisclosed gravity of the dangerous side effects and marginal benefits that this drug presents to the patient population. This is a violation of Okla. Stat. Title 15 §§ 752-53.

7. The Defendant falsely and deceptively misrepresented or knowingly omitted, suppressed, and/or concealed facts of such materiality regarding the safety and efficacy of Vioxx. But for such misrepresentations and omissions, citizens of Oklahoma such as Plaintiff's beneficiaries would not have sought, Oklahoma physicians would not have prescribed, and Plaintiff would not have paid for the drug at all, or would have paid for a substantially less expensive alternate medication. This constitutes a violation of Okla. Stat. Title 15 §§ 752-53.

8. The Defendant purposefully minimized the side effects or provided misinformation about adverse reactions and potential harms from Vioxx, and Defendant succeeded in persuading large segments of the medical community to prescribe and pay for this drug despite both a lack of superior efficacy to existing treatments and unacceptably dangerous side effects as set forth herein. This is a violation of Okla. Stat. Title 15 §§ 752-53.

9. The Defendant had *a duty* to warn that Vioxx users had exhibited repeated instances of serious and often deadly side effects. This is a violation of Okla. Stat. tit. 15 §§ 752-53.

10. The Defendant's actions as set forth herein constitute the knowing omission, suppression, or concealment of material facts, made with the intent that others will rely upon such concealment, suppression, or omission, in connection with the marketing of Vioxx. This is a violation of Okla. Stat. Title 15 §§ 752-53.

11. The Defendant's actions as described above evidence lack of good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commercial practices. This is a violation of Okla. Stat. Title 15 §§ 752-53.

12. Under OCPA, "The commission of any act or practice declared to be a violation of the Consumer Protection Act shall render the violator liable to the aggrieved consumer for the payment of actual damages sustained by the customer and costs of litigation including reasonable attorney's fees, and the aggrieved consumer shall have a private right of action for damages, including but not limited to, costs and attorney's fees." Okla. Stat. Title 15 § 761.1.

13. "Unconscionable" commercial practices make the Defendant liable to Plaintiff under Okla. Stat. Title 15 § 753, which provides that the violator is "liable to the aggrieved customer for the payment of a civil penalty . . . in a sum set by the court of not more than Two Thousand Dollars ($2,000.00) for each violation." *See* Okla. Stat. Title 15 § 761.1.

14. As a direct and proximate result of the Defendant`s wrongful conduct in violation of OCPA, Plaintiff has sustained financial losses in amounts as will be established at the trial of this matter, including paying for Vioxx that they would not have otherwise paid and economic losses incurred by paying a premium price for Vioxx, as opposed to other viable, less expensive, pharmaceutical

treatments. Plaintiff is entitled to recover from the Defendant all such losses.

15. The Defendant is liable to Plaintiff for its reasonable attorneys' fees, filing fees, and costs. *See* Okla. Stat. Title 15 § 761.1; *see also Tibbetts v. Sight 'n Sound Appliance Ctrs., Inc.*, 6 P.3d 1064, (Okla. Civ. App., 1999) (The plain language of the Consumer Protection Act (Act) entitled consumers to costs and attorney's fees in their suit, despite being awarded no damages, because defendant retailer was found to have violated the Act).

C. THIRD CAUSE OF ACTION: UNJUST ENRICHMENT

1. Plaintiff re-alleges and incorporates all preceding paragraphs of this Complaint as if fully set forth here, and further allege as follows:

2. Under Oklahoma law, the elements of unjust enrichment are: (1) an enrichment to the adverse party; (2) an impoverishment to the claimant; (3) a connection between the enrichment and impoverishment; (4) an absence of justification; and (5) an absence of remedies at law. *See* 66 Am. Jur. 2d Restitution and Implied Contracts § 12 (2001).

3. Oklahoma courts state that unjust enrichment "describes a condition resulting from the failure of a party to make restitution in circumstances where it is inequitable." *Lapkin v. Garland Bloodworth, Inc.,* 23 P.3d 958 (Okla. Civ. App. 2000). "A right of recovery under the doctrine of unjust enrichment is essentially equitable; its basis being that in a given situation it is contrary to equity and good conscience for one to retain a benefit which has come to him at the expense of another." *N.C. Corff Partnership, Ltd. v. OXY USA, Inc.,* 929 P.2d 288, 295 (Okla.

Civ. App. 1996). *See also Clay v. Independent School Dist. No. 1 of Tulsa City.*, 935 P.2d 294, 301 n. 11 (Okla. 1997); *French Energy Inc. v. Alexander,* 818 P.2d 1234, 1237 (Okla. 1991). Simply stated, under Oklahoma law a claim for unjust enrichment requires a plaintiff to prove "enrichment to another coupled with a resulting injustice." *Teel v. Pub. Serv. Co. of Okla.*, 1985 OK 112, 767 P.2d 391, 398 (Okla. 1985).

4. The Defendant has been enriched from the manufacture and sale of a dangerous and ineffective drug, and Plaintiff has been correspondingly impoverished or otherwise sustained losses by purchasing or paying for this drug and/or paying an unjust premium price for the product as opposed to other viable, less expensive, pharmaceutical treatments that would not have killed or maimed its clients and citizens of Oklahoma, and/or for medical expenses incurred by its clients after suffering from heart attacks and strokes caused by the ingestion of Vioxx.

5. There is no justification or cause for Defendants' enrichment or Plaintiff's resulting impoverishment.

6. Defendants' enrichment at the expense or impoverishment of Plaintiff is inequitable.

7. Plaintiff demands that Defendant return all such monies acquired from Plaintiffs through the selling of Vioxx.

8. As a direct and proximate result of the Defendant`s wrongful conduct in violation of OCPA, Plaintiff has sustained financial losses in amounts as will be established at the trial of this matter, including paying for Vioxx that they would

not have otherwise paid and economic losses incurred by paying a premium price for Vioxx, as opposed to other viable, less expensive, pharmaceutical treatments. Plaintiff is entitled to recover from the Defendant all such losses.

D. FOURTH AND FIFTH CAUSES OF ACTION: DECEIT/FRAUD, AND MISREPRESENTATION

1. Plaintiff re-alleges and incorporates all preceding paragraphs of this Complaint as if fully set forth here, and further allege as follows:

2. Oklahoma makes it illegal to engage in deceit, fraud, or misrepresentation, and defines deceit as: (1) The suggestion, as a fact, of that which is not true by one who does not believe it to be true; (2) The assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true; (3) The suppression of a fact by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact. *See* Okla. Stat. Title 76 § 3.

3. In Oklahoma, the elements of actionable fraud are (1) the defendant made a material representation that was false, (2) he knew when he made the representation that it was false, (3) he made it with the intention that it should be acted upon by plaintiff, and (4) plaintiff acted in reliance upon it and thereby suffered detriment. *See Silk v. Phillips Petroleum Co.,* P12, 760 P.2d 174, 176-77 (OK 1998).

4. The Defendant made many material misrepresentations to Plaintiff, its agents and beneficiaries, physicians who prescribe the medications for which Plaintiff pays, and to Oklahoma citizens who sought and used Vioxx, as to the safety and

efficacy of its product Vioxx that it knew and/or should have known were false at the time made. The Defendant made these material misrepresentations as to the safety and efficacy of its product Vioxx in full knowledge and intention that they be relied upon by Plaintiff, its agents, intermediaries and beneficiaries.

5. The Defendant's actions as set forth herein constitute knowing omission, suppression, or concealment of material facts, made with the intent that others will rely upon such concealment, suppression, or omission, in connection with the marketing of Vioxx.

6. As a direct and proximate result of the Defendant`s wrongful conduct, and in complete and foreseeable reliance upon such conduct, Plaintiff has sustained financial losses in amounts as will be established at the trial of this matter, including paying for Vioxx that they would not have otherwise paid and economic losses incurred by paying a premium price for Vioxx, as opposed to other viable, less expensive, pharmaceutical treatments. Plaintiff is entitled to recover from the Defendant all such losses.

E. SIXTH CAUSE OF ACTION: NEGLIGENT MISPRESENTATION

1. Plaintiff re-alleges and incorporates all preceding paragraphs of this Complaint as if fully set forth here, and further allege as follows:

2. Merck is liable to Plaintiff for common law negligent misrepresentation.

3. The Defendant had *a duty* to warn which arose when it knew, or with reasonable care should have known, that Vioxx users had exhibited repeated instances of serious and often deadly side effects.

4. The Defendant's actions as set forth herein constitute knowing omission, suppression or concealment of material facts, made with the intent that others will rely upon such concealment, suppression, or omission, in connection with the marketing of Vioxx. *See Schulte v. Apache Corp.*, 949 P.2d 291, 296 (Ok. 1994) ("Estoppel, constructive fraud, and negligent misrepresentation all require that a party rely to that party's detriment on the actions or words of the other party").

5. As a direct and proximate result of the Defendant`s wrongful conduct, Plaintiff has sustained financial losses in amounts as will be established at the trial of this matter, including paying for Vioxx that they would not have otherwise paid and economic losses incurred by paying a premium price for Vioxx, as opposed to other viable, less expensive, pharmaceutical treatments. Plaintiff is entitled to recover from the Defendant all such losses. Plaintiff has also been forced to pay for related health problems following heart attacks and strokes by its clients and citizens of Oklahoma. Plaintiff is entitled to recover from the Defendant all such losses.

F. SEVENTH AND EIGHTH CAUSES OF ACTION: NEGLIGENCE AND GROSS NEGLIGENCE

1. Plaintiff re-alleges and incorporates all preceding paragraphs of this Complaint as if fully set forth here, and further allege as follows:

2. Merck's conduct constituted a departure from that which a person of ordinary prudence would do under the same or similar circumstances. As such, Merck is liable for negligence.

3. Merck, as a manufacturer "has a duty to those who may foreseeably be expected

to use his products . . . to exercise reasonable care in the design and manufacture of those products." *Pickens v. Tulsa Metro. Ministry*, 951 P.2d 1079, 1083, 1088 (Ok. 1997) (stating that the threshold question is whether the defendant has a duty to the particular plaintiff alleged to have suffered an injury).

4. Defendant Merck, as a pharmaceutical manufacturer and distributor, and had a duty to warn Plaintiff and citizens of Oklahoma of adverse drug reactions, which it knew, or had reason to know, were inherent in the use of its product. Further, in light of their knowledge, Merck had a duty to timely warn Plaintiff and citizens of Oklahoma of the known or suspected risks.

5. The Defendant committed numerous acts of negligence in the manufacturing, distributing, promoting and offering its product for sale, including, but not limited to, the following:

a. failing to timely warn consumers of the actual and known risks of serious cardiovascular events inherent in the use of Vioxx; and

b. Promoting use of its product in a fraudulent manner, despite evidence as to its dangerousness due to its association with serious cardiovascular events.

6. As a proximate result of the negligence and gross negligence of Merck, its agents, and employees, Plaintiff suffered damages. For such negligence, Plaintiff respectfully seeks all of the damages to which it may be legally entitled.

G. NINTH CAUSE OF ACTION: BREACH OF IMPLIED/EXPRESS WARRANTY

1. Plaintiff re-alleges and incorporates all preceding paragraphs of this Complaint as if fully set forth here, and further allege as follows:

2. Under Oklahoma law, "Any distinct assertion or affirmation as to the quality or character or the thing to be sold, made by the seller during the negotiations for the sale, which it may reasonably be supposed was intended to induce the purchase and was relied on by the purchaser, will be regarded as a warranty unless accompanied by an express statement that it is not intended as such. If the affirmation was made in good faith, it is still a warranty. If made with a knowledge of its falsity, it is none the less a warranty, though it is also a fraud." *Wilson v. Moran*, 82 Okla. 34, 42 (1921

3. Merck, at all times the drug Vioxx was on the market, actively sought to directly induce Plaintiff's employees, agents and beneficiaries; physicians who prescribe drugs to clients and are paid by Plaintiff; customers who received drugs from state agencies; agents of state entities who pay for drugs to Plaintiff's beneficiaries and citizens of Oklahoma; and other governmental entities—to purchase, prescribe, and/or use Vioxx.

4. Merck, at all times the drug Vioxx was on the market, actively warranted to Plaintiff's employees, agents and beneficiaries; physicians who prescribe drugs to clients of state agencies; beneficiaries who received drugs from state agencies; agents of state entities who pay for drugs to clients and citizens of Oklahoma; and other governmental entities—as to the safety and efficacy of Vioxx, and omitted the devastating effects of Vioxx.

5. But for Merck's false representations and false warranties, Plaintiff, Plaintiff's employees, and agents would not have included Vioxx in its list of approved drugs.

6. But for Merck's false representations and false warranties, physicians would not have prescribed Vioxx to those whom Plaintiff paid for prescriptions.

7. But for Merck's false representations and false warranties, Plaintiff's beneficiaries would neither have requested nor been given Vioxx.

8. As a direct and proximate result of the Defendant`s false warranties, Plaintiff has sustained financial losses in amounts as will be established at the trial of this matter, including paying for Vioxx that they would not have otherwise paid and economic losses incurred by paying a premium price for Vioxx, as opposed to other viable, less expensive, pharmaceutical treatments. Plaintiff is entitled to recover from the Defendant all such losses. Plaintiff is entitled to recover from the Defendant all such losses.

H. TENTH CAUSE OF ACTION: PRODUCT LIABILITY

1. Plaintiff re-alleges and incorporates all preceding paragraphs of this Complaint as if fully set forth here, and further allege as follows:

2. Oklahoma law "generally requires a manufacturer to warn consumers of danger associated with the use of its product to the extent the manufacturer knew or should have known of the danger." *Kirkland v. General Motors*, 521 P.2d 1353 (Okla. 1974).

3. Merck knew or should have known of the dangers related to the ingestion of VIOXX.

4. "When a manufacturer sells a product in a defective condition which makes it unreasonably dangerous, and the product causes physical harm to the user of

the product, the manufacturer can be held responsible for the damage caused if the product reaches the user without substantial change." Section 402A of the Restatement (Second) of Torts; *Kirkland v. General Motors Corporation*, 521 P.2d 1353 (Okla. 1974)

5. As a direct and proximate result of the Defendant`s production, marketing and sale of Vioxx, Plaintiff has sustained financial losses in amounts as will be established at the trial of this matter, including paying for Vioxx that they would not have otherwise paid and economic losses incurred by paying a premium price for Vioxx, as opposed to other viable, less expensive, pharmaceutical treatments. Plaintiff is entitled to recover from the Defendant all such losses. Plaintiff is entitled to recover from the Defendant all such losses

VIII. DAMAGES

1. Plaintiff fully incorporates the preceding paragraphs by reference.

IX. JURY DEMAND

1. Plaintiff hereby requests that all causes of actions alleged herein be tried before a jury consisting of citizens residing in Oklahoma. Plaintiff is tendering the appropriate jury fee.

XI. PRAYER

WHEREFORE, Plaintiff prays as follows:

1. That the unlawful conduct alleged herein be adjudged and decreed to be

unlawful and unfair methods of competition and/or unfair and deceptive acts or practices committed by Defendant as prohibited Oklahoma law;

2. That, pursuant to OCPA, the unlawful conduct committed by Defendant as alleged herein be adjudged and decreed to have been entered into by Defendant with the intent to defraud;

3. That, pursuant to OCPA, for each act of unlawful conduct committed by Defendant as alleged herein, the court impose a penalty of two thousand dollars payable to Plaintiffs;

4. That, pursuant to OCPA, the Defendant be found liable to Plaintiffs for financial restitution and such other ancillary monetary damages sustained by Plaintiff, all of which will be established at the trial of this matter;

5. That, pursuant to the ODTPA, Okla. Stat. Title 78, § 51 et seq., the Court, in its discretion, award reasonable attorneys' fees to the Plaintiff. Even if Defendant did not "willfully" engage in deceptive trade practices, Plaintiff prays that the Court, in its discretion as authorized by the Oklahoma Deceptive Trade Practices Act, Okla. Stat. Title 78, § 51 et seq., award attorney fees to the Plaintiff.

6. That, pursuant to the ODTPA and OCPA, Defendant be found liable to Plaintiff for any and all economic damages including actual damages, exemplary damages, costs of suit and attorneys' fees;

7. That Plaintiff be granted all damages to which they are reasonably entitled, including, but not limited to, the return of the purchase price paid by Plaintiff for Vioxx prescriptions, attorney's fees to the full extent recoverable, all costs, and legal interest from the date of judicial demand until paid, due to Vioxx's defects,

Defendant's deceptive and unfair trade practices, Negligence, Defendant's misrepresentations, and/or the Defendant's unjust enrichment, and Defendant's violations of other statutory and common law duties

8. Plaintiff prays that all deposition and travel expenses be taxed as costs.

9. Plaintiff further prays for any and all such other, further, and different relief as the nature of the case may require or as may be deemed just and proper by this Court.

Respectfully submitted,

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